



National Health and Nutrition Examination Survey (NHANES)

Respiratory Health Spirometry Procedures Manual



January 2008



TABLE OF CONTENTS

<u>Chapter</u>		<u>Page</u>
1	SPIROMETRY OVERVIEW	1-1
	1.1 Overview of the Spirometry Exam Component.....	1-1
	1.2 The Bronchodilator Subcomponent	1-2
	1.3 Chronic Obstructive Pulmonary Disease	1-3
	1.4 Asthma	1-4
	1.5 Basics of Respiration	1-5
	1.6 Spirometric Measurements	1-6
	ACKNOWLEDGMENTS AND REFERENCES.....	1-13
2	EQUIPMENT AND SUPPLIES	2-1
	2.1 List of Equipment and Supplies	2-1
	2.2 Description of Equipment and Supplies	2-2
	2.2.1 Equipment	2-2
	2.2.2 Supplies.....	2-3
	2.3 Equipment Setup Procedures	2-4
	2.3.1 Equipment	2-4
	2.3.2 Supplies.....	2-6
	2.4 Equipment Care and Maintenance	2-6
	2.4.1 Spirometer.....	2-6
	2.4.2 Hoses	2-7
	2.5 Equipment Packup Procedures	2-7
	2.5.1 Equipment	2-8
	2.5.2 Supplies.....	2-8
3	EXAMINATION PROTOCOL	3-1
	3.1 Eligibility Criteria for Spirometry and Bronchodilator Components	3-1
	3.2 Spirometry Safety Exclusion Questions	3-1
	3.3 Spirometry Examination Procedures	3-6
	3.3.1 Spirometry Testing Procedures	3-7

TABLE OF CONTENTS (continued)

<u>Chapter</u>		<u>Page</u>
	3.3.2 Instruction and Preparation	3-8
	3.3.3 Initiate Test	3-10
	3.3.4 End of Test	3-16
	3.3.5 Procedures for Repeat Spirometry Testing	3-18
	3.4 Troubleshooting Spirometry Examinations	3-20
	3.5 Report of Findings	3-22
4	QUALITY CONTROL	4-1
	4.1 Equipment Cleaning and Calibration	4-1
	4.1.1 Quality Control Checks Screens	4-1
	4.1.2 Equipment Cleaning	4-5
	4.1.3 Equipment Calibration	4-5
	4.2 Equipment Maintenance	4-8
	4.3 Review of Results During the Exam	4-8
	4.4 Observation	4-9
	4.5 Review of Exam Status	4-9
	4.6 Review of Results During Analysis	4-9
	4.7 NIOSH Quality Control Reports	4-10
	4.7.1 Operator Reports	4-10
	4.7.2 Statistics	4-11
	4.7.3 Grades	4-11
	4.7.4 Summary and Trend Analysis Reports	4-11
5	SAFETY PROCEDURES	5-1
	5.1 Spirometry Safety Precautions	5-1
	5.1.1 Safety Exclusion Screening	5-1
	5.1.2 Infection Control Measures	5-1
	5.1.3 Prevention of Electric Shock	5-2
	5.2 Standing vs. Sitting During Spirometric Testing	5-2
	5.3 Comprehension or Language Difficulties	5-3
	5.4 Emergency Procedures	5-3

TABLE OF CONTENTS (continued)

List of Appendixes

<u>Appendix</u>		<u>Page</u>
A	NIOSH Spirometry System Design Criteria	A-1
B	Screenshots for Spirometry Safety Exclusion Questions.....	B-1

List of Tables

<u>Table</u>		
1-1	Lung diseases and spirometry results	1-12
3-1	Spirometry safety exclusion items by age	3-2

List of Figures

<u>Figure</u>		
1-1	The respiratory tract.....	1-5
1-2	Normal volume-time curve	1-8
1-3	Normal flow-volume curve.....	1-8
1-4	FVC and FEV1 on a normal volume-time curve	1-9
1-5	FVC on normal flow-volume curve	1-9
1-6	Normal and restrictive patterns volume-time curves	1-10
1-7	Flow-volume curves	1-10
1-8	Obstructive pattern shown on a volume-time curve	1-11
1-9	Obstructive pattern shown on a flow-volume curve	1-11

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

<u>Exhibit</u>		<u>Page</u>
3-1	Aneurysm help screen.....	3-3
3-2	Spirometry exclusion	3-4
3-3	End of subsection screen.....	3-4
3-4	End of exam screen.....	3-5
3-5	Begin spirometry test screen.....	3-6
3-6	OMI/NIOSH main program screen.....	3-7
3-7	Proceed with testing screen.....	3-8
3-8	Curve display screen – pre-test	3-10
3-9	Curve display screen	3-11
3-10	Test results screen.....	3-12
3-11	Results and quality code box	3-13
3-12	Override acceptability code screen	3-15
3-13	Post-Test data screen	3-16
3-14	End of subsection – complete screen	3-17
3-15	End of exam screen.....	3-18
3-16	Technologist bronchodilator referral script screen	3-19
3-17	End of exam – SP to bronchodilator screen.....	3-19
4-1	Quality Control Checks – Start of Stand QC	4-2
4-2	Quality Control Checks – Daily QC	4-2
4-3	Quality Control Checks – Start of Session QC	4-3
4-4	Quality Control Checks – Weekly QC.....	4-3

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

<u>Exhibit</u>		<u>Page</u>
4-5	Quality Control Checks – End of Stand QC	4-4
4-6	Quality Control Checks – Not Done QC	4-4
4-7	Operator Report	4-10
4-8	Quality Control Summary Report.....	4-12
4-9	Calibration Summary Report.....	4-12
4-10	Trend Analysis Report.....	4-13

1. SPIROMETRY OVERVIEW

1.1 Overview of the Spirometry Exam Component

Spirometry, which means “the measuring of breath,” is a routinely used pulmonary function test (PFT) that measures the amount and speed of air that a person can inhale and exhale. Results from the test can be used to estimate lung function and aid in the diagnosis of certain respiratory disorders. The current NHANES spirometry component is sponsored by the Centers for Disease Control and Prevention, National Institute for Health Statistics (CDC/NCHS), the National Heart, Lung, and Blood Institute (NHLBI), and the National Institute for Occupational Safety and Health (NIOSH). The objective of the 2007-8 spirometry data collection cycle is to assess the prevalence of asthma and adult chronic obstructive pulmonary disease (COPD) in the U.S. population. The data will also be used to produce updated spirometric reference data for the general population. Moreover, comparisons of 2007-8 data with that of previous studies will illuminate trends in asthma and COPD prevalence over time in the United States.

Prior to the current survey, NHANES III (1988-1994) also included a spirometry component.¹ These spirometry data were used to generate age, gender, and race/ethnicity specific prediction equations for normal spirometric values.² These reference standards have been widely used in research relating to occupational pulmonary disease, the effects of air quality on spirometric function, and in particular the relationship of smoking to COPD. The data from the NHANES III survey have been used also in evaluation of asthma and COPD prevalence and their risk factors in the general U.S. population.^{3,4}

All sample persons (SPs) aged 6-79 years will be eligible to participate in the spirometry component. The procedures are based on the current standards for pulmonary function, equipment, testing, and interpretation set by the American Thoracic Society (ATS).^{5,6} Spirometry training is required for all health technologists and will be provided by NIOSH.

Spirometry is part of the Respiratory Health (RH) component, together with Exhaled Nitric Oxide (ENO) testing (please refer to the *ENO Procedures Manual* for further details). The spirometry component will include a subcomponent in which the spirometry exam will be repeated on a small subset of participants following the administration of a bronchodilator medication. This will make it possible to distinguish between COPD and asthma, which have similar baseline spirometry profiles but differ in post-

bronchodilator spirometry testing. This distinction is important because, although asthma and COPD have similar symptoms, they are associated with different risk factors and molecular and patho-physiologic mechanisms. The bronchodilator evaluation will be conducted by the MEC physician (see *Bronchodilator Component Procedures Manual* for details).

1.2 The Bronchodilator Subcomponent

The main difference between the 2007 spirometry component and spirometry during NHANES III is the addition of the bronchodilator subcomponent. Participants whose baseline spirometry results show lung function values below a certain threshold will be asked to repeat spirometry after inhaling a β_2 -adrenergic bronchodilator medication that acts to open constricted airways. Typically, asthma patients show marked improvements in post-bronchodilator spirometry testing, while patients with COPD exhibit little, if any, response to the medication. Therefore, results from repeat spirometry testing following the bronchodilator could potentially provide a more detailed picture of each individual's breathing problem, i.e., an indication of whether the person is likely to have asthma or COPD.

In clinical settings, spirometric testing using β_2 -adrenergic bronchodilator administration has been routinely employed to diagnose asthma in both children and adults since the 1970s. Moreover, albuterol inhalers have been approved for administration to persons 4 years of age and older. Further, current U.S. National Heart, Lung and Blood Institute (NHLBI) Expert Panel Report Guidelines for the Diagnosis and Management of asthma⁷ state that post-bronchodilator spirometry testing is essential for the initial diagnosis of asthma; hence, its routine diagnostic use in both children and adults is considered a clinical standard or "best practice." The American Thoracic Society has described standards for the interpretation of bronchodilator response testing.^{8,9}

The addition of spirometry to NHANES in 2007 marks the first year that a bronchodilator medication has ever been administered in the survey. However, spirometry with post-bronchodilator testing has been successfully employed in many major population-based surveys, in both children and adults. A major example for children is the Southwestern Children's Respiratory Study in Arizona, a continuous longitudinal community-based study of 1,250 children studied from birth in 1980 to the present.¹⁰ For adults, major current examples are the European Community Respiratory Health Survey of men and women at 36 sites in the European Union,¹¹ and the Platino Project, a multicountry survey in Latin American urban settings.¹² Currently, the Framingham, Massachusetts study is also deploying post-

bronchodilator spirometry.¹³ We have derived our safety exclusion protocols for bronchodilator administration based on these and other epidemiological studies.

In summary, bronchodilator testing is not planned to be administered to healthy participants, but only to a survey subpopulation with abnormal baseline spirometry (i.e., those persons with a high likelihood of clinical obstructive respiratory disease). This subgroup is intended to be similar to the set of respiratory disease patients who would routinely receive such testing in clinical settings.

Since a β_2 -adrenergic bronchodilator is a prescription medication, the MEC physician will administer the bronchodilator only after he or she obtains informed consent and completes a review of safety exclusions that would prohibit the participant from taking the medication. For example, individuals who are taking particular types of medications (e.g., antiarrhythmics, anticonvulsants, and some antidepressants) or who have certain heart conditions (i.e., high blood pressure, high pulse, etc.), will be excluded from the bronchodilator portion of spirometry for safety reasons.

1.3 Chronic Obstructive Pulmonary Disease

The term chronic obstructive pulmonary disease (COPD) refers to a group of conditions characterized by progressive development of airflow limitation that is usually not fully reversible with medication treatment. Chronic obstructive bronchitis and emphysema are two serious conditions that cause COPD. Although both conditions may result in irreversible airway obstruction, they exhibit different pathologic mechanisms leading to COPD. For example, in chronic bronchitis, airflow limitation is caused by obstruction of small airways in the lung due to inflammation and excessive bronchial mucus secretion. In emphysema, airflow limitation is caused by the destruction of elastic tissue in the respiratory part of the lung where gas exchange occurs (respiratory bronchioles and alveoli), resulting in air trapping and decreased oxygen to the body.

COPD is a serious public health problem in the United States and is responsible for extensive morbidity and mortality in the American population. According to the most recent NCHS statistics (based on data from 2002), COPD is the fourth leading cause of death in the United States and was responsible for 124,816 American deaths in 2002.¹⁴ In fact, this statistic is probably an underestimation of COPD mortality since the disease is often a cofactor in other leading causes of death

such as heart disease. Despite the important role of genetic and environmental factors in causing COPD, most cases are related to cigarette smoking or other environmental exposures, and thus are preventable.

Because COPD is a major cause of death in the United States, there is a need for continued monitoring of its prevalence in the general population. The inclusion of spirometry in the current NHANES survey will lead to more up-to-date and detailed estimates of the nationwide prevalence of and risk factors for COPD.

1.4 Asthma

Both asthma and COPD are characterized by chronic airway inflammation. However, the inflammatory mechanisms and general disease profiles of the two conditions are very different. As a result, COPD and asthma affect different types of people and respond to different types of treatment.

Asthma has many different clinical manifestations but is generally characterized by airflow obstruction, bronchial hyper-responsiveness, and airway inflammation. Similar to COPD, asthma is caused by a combination of genetic and environmental factors. Unlike COPD, however, the inflammatory reaction involved in asthma may often be an allergic-type reaction, meaning that the inflammatory response (or asthma attack) can be brought on by the inhalation of some sort of allergen.

Asthma is widely prevalent in the American population. According to self-reported data from the 2004 National Health Interview Survey, approximately 7.3 percent of the U.S. population suffers from asthma, and prevalence is higher among children than adults. The addition of spirometry into the current NHANES will provide new evidence-based information about the nationwide prevalence of asthma in both children and adults.

One treatment for asthma is the administration of β_2 -adrenergic inhalants (bronchodilators), which act quickly and effectively to open constricted airways. Conversely, β_2 -adrenergic inhalants have little or no effect among patients with COPD. This allows diagnoses of asthma and COPD to be distinguished based on a subject's response to the inhaled bronchodilator. The inclusion of the bronchodilator portion of the new spirometry component will allow for separate analyses of the prevalence of asthma and COPD in NHANES data output.

1.5 Basics of Respiration

The respiratory tract consists of the trachea, lungs, bronchi, bronchioles, and alveoli as shown in Figure 1-1. The alveoli constitute both the functional unit of the lung and the site of cellular

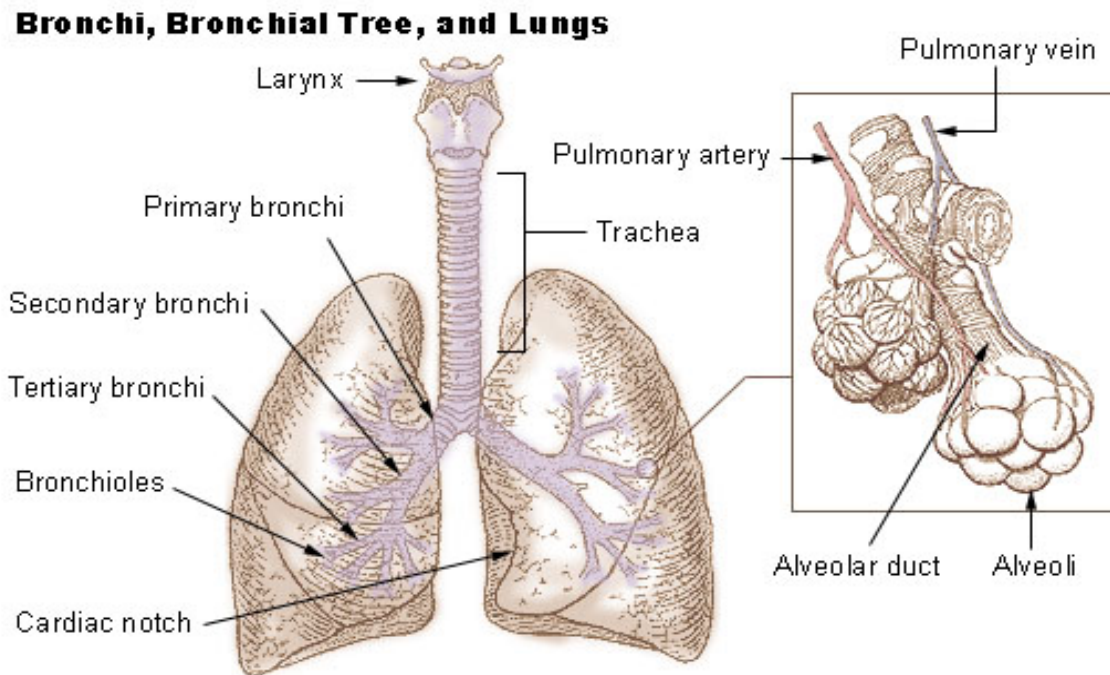


Figure 1-1. The respiratory tract

respiration. From the trachea, the airways divide progressively like branching trees in both symmetrical and asymmetrical fashion: each branch of airways leading away from the trachea becomes smaller, but in turn the total area of cross-sectional airways actually increases. As a result, airflow resistance decreases as air moves from the large airways to the smaller bronchioles.

The movement of air in and out of the lungs is called ventilation, that includes both inspiration and expiration. Inspiration, or inhalation, is an active process that utilizes muscles in the chest, primarily the diaphragm. Expiration, or exhalation, is normally a passive process that requires little muscular activity unless air is forcefully expelled from the lungs, such as during a forced vital capacity maneuver (see Section 1.6). The main purpose of the respiratory tract is to conduct air between the external environment and the surface of the alveoli to permit an exchange of oxygen and carbon dioxide.

Spirometry testing does not directly measure the rate of oxygen transfer to the lungs; rather it measures lung volume and air flow rates, which are major factors that influence the process of oxygen transfer.

The exchange of oxygen from the outside environment for carbon dioxide from venous blood defines the fundamental process of respiration. This exchange occurs at the surface of each of the approximately 300 million alveoli contained in the lungs. The alveoli have a combined total surface area for gas exchange that is equivalent to the size of a tennis court.

The lung is served by two blood supplies: pulmonary and bronchial. Pulmonary circulation pumps oxygen-depleted venous blood from the heart through the pulmonary arteries and to the lungs to be oxygenated before being pumped by the heart to the rest of the body. Bronchial circulation arises from the aorta (the largest artery coming from the heart) and pumps oxygenated blood to the lungs, providing the primary supply of blood for the lung tissue itself.

Finally, it is important to remember that, while the main purpose is to facilitate the transfer of oxygen and carbon dioxide, the lung also serves other functions: metabolism and detoxification of a wide range of substances; protection against infectious agents and environmental pollutants; and the synthesis of important compounds such as prostaglandins, which are important in inflammatory reactions.

1.6 Spirometric Measurements

The NHANES spirometry protocol relies on certain standard spirometric measurements to assess lung function. Participants perform the spirometry test using a **spirometer**, a device that measures the amount of air a subject exhales and the rate at which he or she exhales the air. The basic standard spirometric test requires the subject to exhale as forcefully as possible after taking in a full, deep breath. The subject's effort is called the **forced expiratory maneuver**. In the current NHANES, each participant's individual spirometric measurements are compared to standards established from NHANES III data.² These standards are calculated based on an individual's age, height, sex, and race/ethnicity since the diagnostic thresholds for obstructive lung disease differ by body size and by demographic subgroups. The following standard measurements will be used in the NHANES spirometry component:

Forced Vital Capacity (FVC): The maximum volume of air exhaled forcefully after a maximal inspiration. For adults, this forced exhalation should last at least 6 seconds; however, persons

with COPD may take considerably longer to exhale all their air. Children under the age of 10 should be coached to exhale for at least 3 seconds.

NOTE: FVC should not be confused with vital capacity (VC), which is defined as the maximum amount of air that the subject can breathe out after the deepest inspiration, *whether or not* the air was exhaled forcefully. In subjects without airway obstruction, the FVC is usually equal to the VC. Also, some residual air always remains to keep the lungs partially inflated even after a maximum FVC maneuver is completed; thus, the FVC does not measure the total lung volume.

Forced Expiratory Volume in One Second (FEV1): The volume of air exhaled during the first second of a forced expiratory maneuver. Normally, a healthy person can be expected to exhale from 70 to 80 percent of the FVC in the first second of a forced expiration maneuver.

Peak Expiratory Flow (PEF): The highest instantaneous airflow rate measured during the FVC maneuver. PEF is measured in liters per second and will be used mainly to assess participant effort.

In the current NHANES spirometry study, the primary measurement used to assess obstructive lung disorders will be the ratio of forced expiratory volume in 1 second to forced vital capacity expressed as a percentage, or **FEV1/FVC%**. Sample persons will be assigned to the bronchodilator subcomponent for further testing if their baseline spirometric testing results exhibit the following:

- FEV1/FVC% less than the Lower Limit of Normal (LLN) determined for their age, height, sex, and race/ethnicity or
- FEV1 /FVC% less than 70 percent.

Additionally, participants showing a FEV1/FVC% less than 50 percent of that predicted based on their demographic characteristics will automatically be sent to the MEC physician (i.e., persons likely to have severe obstructive lung disease), who will assess whether referral to a community provider is necessary.

Spirometric data are viewed as graphs called **spirograms**. Measurements of exhaled volume (in liters), time (in seconds), and airflow rates (in liters per sec) are determined and displayed on the spirograms. There are two types of spirograms that will be used in the NHANES spirometry component:

- **Volume-Time:** The basic volume vs. time curve contains points corresponding to the FEV1 and FVC and

- **Flow-Volume:** The expiratory flow vs. volume curve displays instantaneous airflow rates as a function of volume exhaled. This curve also contains points corresponding to the PEF and FVC.

Figures 1-2 and 1-3 illustrate a normal volume-time curve and a normal flow-volume curve, respectively.

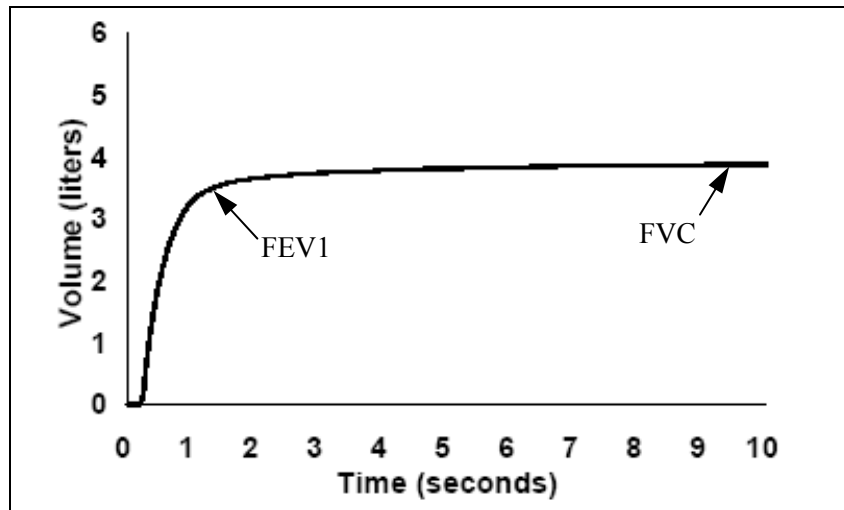


Figure 1-2. Normal volume-time curve

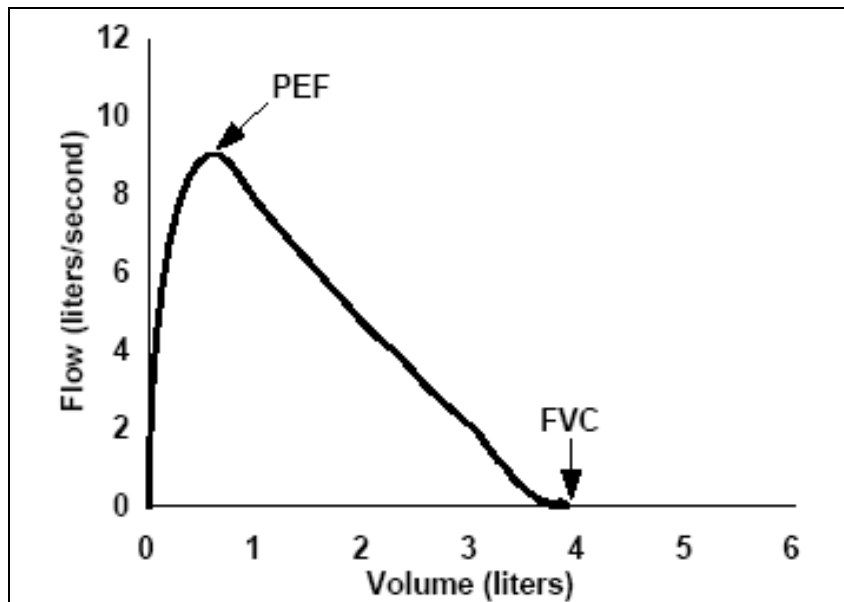


Figure 1-3. Normal flow-volume curve

In the following illustrations, the values for FVC and FEV1 are shown in a normal volume-time curve (Figure 1-4). The FVC is shown again in a flow-time curve (Figure 1-5).

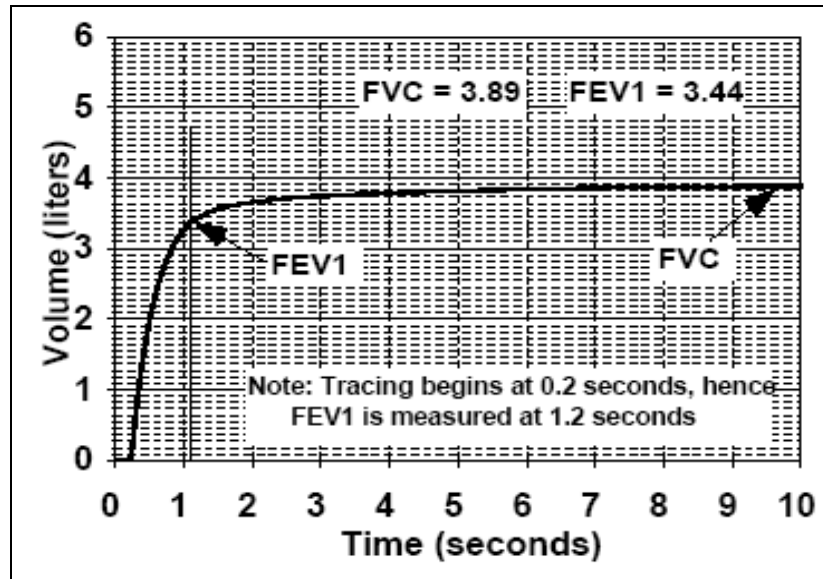


Figure 1-4. FVC and FEV1 on a normal volume-time curve

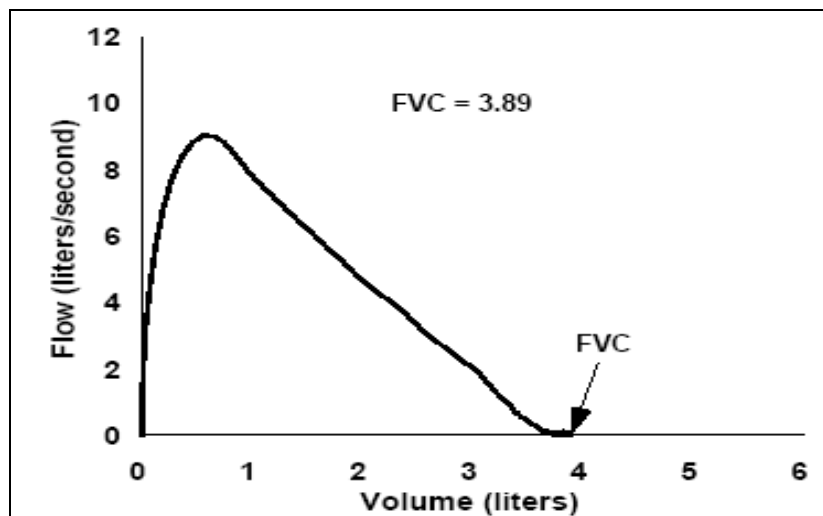


Figure 1-5. FVC on normal flow-volume curve

Spirograms may be used to classify participants as normal, having an obstructive pattern and/or a restrictive pattern. Specifically, a low FVC is indicative of a restrictive disorder, and typically these individuals will also have a low FEV1. A low FEV1/FVC% ratio may indicate an obstructive impairment. On average, typically 70-80 percent of the FVC is exhaled in the first second from a person who is healthy. However, a person with airway obstruction may be able to exhale only 60 percent or less of the FVC in the first second even though the FVC may be normal. Additionally, some persons may show evidence of a combination of both airway obstruction and restrictive disease. Figures 1-6 and 1-7 show examples of normal compared to restricted curves, while Figures 1-8 and 1-9 show examples of curves resulting from persons with obstructive lung disorders.

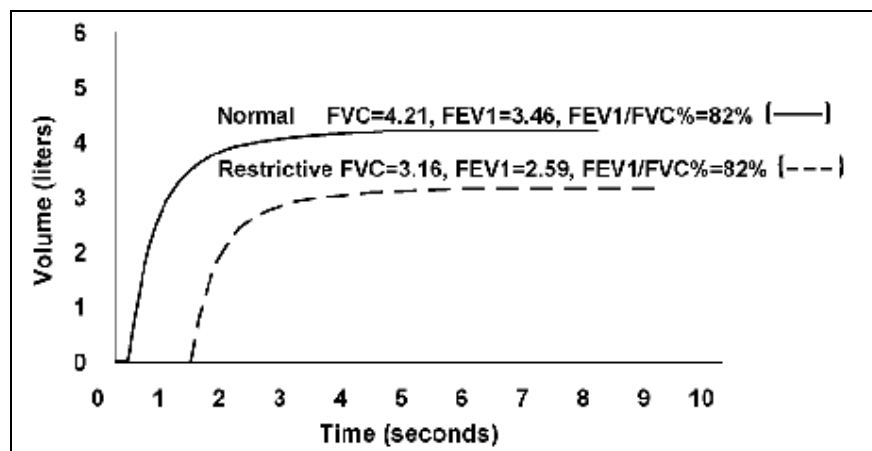


Figure 1-6. Normal and restrictive patterns volume-time curves

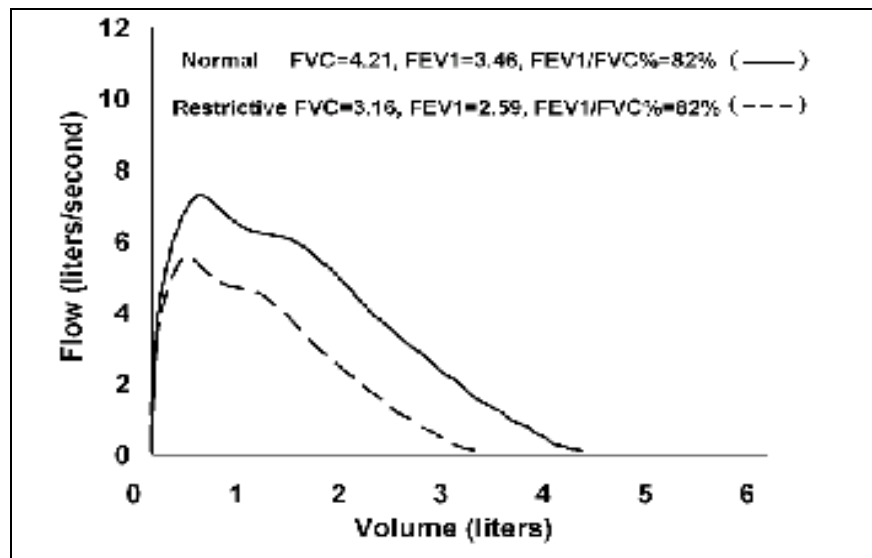


Figure 1-7. Flow-volume curves

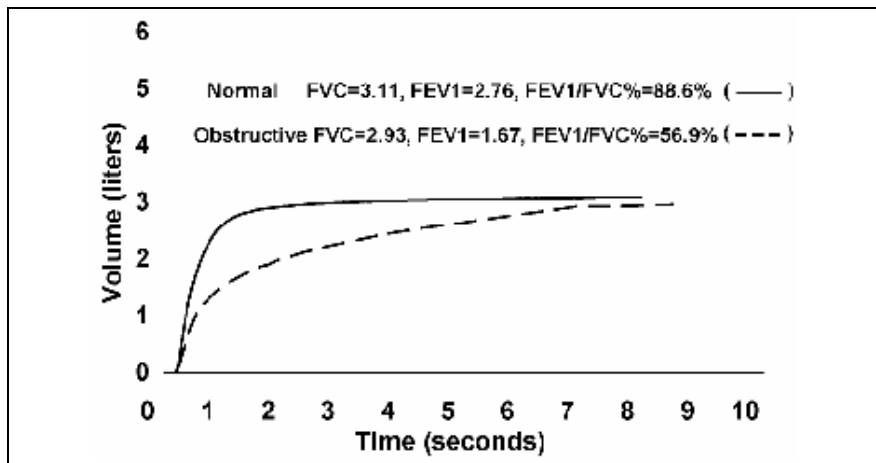


Figure 1-8. Obstructive pattern shown on a volume-time curve

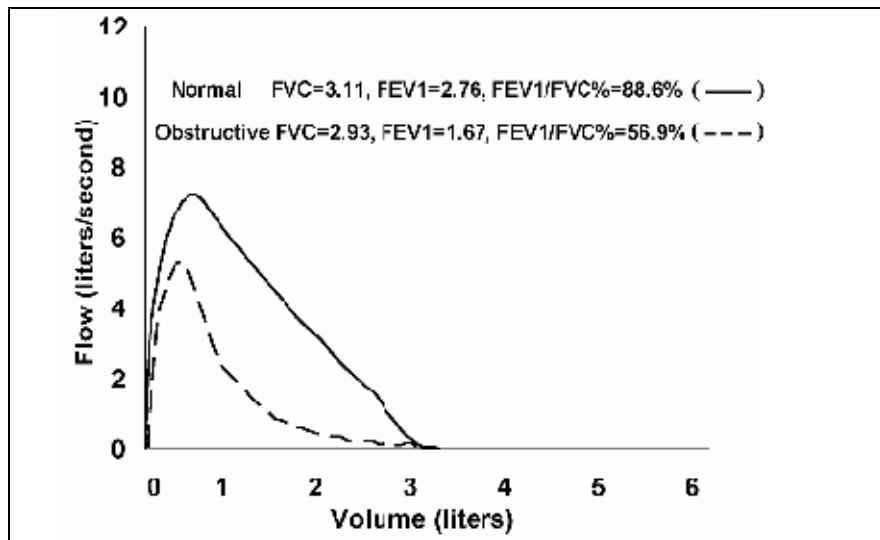


Figure 1-9. Obstructive pattern shown on a flow-volume curve

Although spirometry can provide useful diagnostic and screening information, it has some limitations. Table 1-1 provides a brief interpretation of spirometry results based on values obtained for FVC, FEV1, and FEV1/FVC%. Test results can show restrictive or obstructive disease patterns, but they are not disease-specific. For example, a person's spirogram may show a low FEV1, but a physician may not be able to determine whether the cause is from asthma, chronic bronchitis, or some other obstructive disease. A low FVC (an overall reduction in measured lung volume) may be due to emphysema or to lung scarring such as from asbestos or silica exposure. Additional information, such as a physical examination, chest X-rays, and health and occupational histories, is always needed to make a diagnosis.

Table 1-1. Lung diseases and spirometry results

Interpretation	FVC	FEV1	FEV1/FVC%
Normal spirometry	Normal	Normal	Normal
Airway obstruction	Low or normal	Low	Low
Lung restriction	Low	Low	Normal
Combination of obstruction and restriction	Low	Low	Low

Finally, spirometry can often detect obstructive diseases in their early stages but, for certain restrictive diseases, spirometric testing may not be sensitive enough to show abnormalities before extensive and, in some cases, irreversible damage has been done. For example, signs of overt lung disease and lung scarring may be found on chest X-rays while spirometry results are still normal. Thus, while spirometric testing is important, spirometry should not be used as the sole screening tool of a respiratory disease survey program, or as the sole criterion for a clinical diagnosis of disease.

ACKNOWLEDGMENTS AND REFERENCES

The technical descriptions and documentation of the NIOSH Spirometry System and examination procedures were provided by John Hankinson, Ph.D. from Hankinson Consulting, Inc. and Lu-Ann Beeckman-Wagner, Ph.D, from the NIOSH Laboratory in Morgantown, West Virginia.

1. Third National Health and Nutrition Examination Survey III: Spirometry Procedure Manual. http://www.cdc.gov/nchs/about/major/nhanes/NHANESIII_Reference_Manuals.htm.
2. Hankinson, J.L., Odencrantz, J.R., and Fedan, K.B. (1999). Spirometric reference values from a sample of the general U.S. population. *Am J Respir Crit Care Med*, 159, 179-187.
3. Mannino, D.M., Ford, E.S., and Redd, S.C. (2003, December). Obstructive and restrictive lung disease and functional limitation: data from the Third National Health and Nutrition Examination. *J Intern Med*, 254(6), 540-7.
4. Hnizdo, E., Sullivan, P.A., Bang, K.M., and Wagner G. (2003, October). Association between chronic obstructive pulmonary disease and employment by industry and occupation in the US population: a study of data from the Third National Health and Nutrition Examination Survey. *Am J Epidemiol*, 156(8), 738-46.
5. Miller, M.R., Hankinson, J, Bruasco, V. et. al. (2005). Standardization of Spirometry. No. 2 in the Series ATS/ERS Task Force: Standardization of Lung Function Testing. *Eur Resp J*, 26, 319-338.
6. Miller, M.R., Crapo, R., and Hankinson, J. et al. (2005, July). General considerations for lung function testing. *Eur Respir J*, 26(1), 153-61.
7. NHLBI Expert Panel Report #2: Guidelines for the Diagnosis and Management of Asthma. "Measures of Assessment and Monitoring," pp.17-21, 2002. <http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm>.
8. American Thoracic Society. (1995). Standards for the diagnosis and care of patients with chronic obstructive pulmonary disease. *Am J Respir Crit Care Med*, 152, S77-S120.
9. American Thoracic Society, Medical Section of the American Lung Association. Lung Function Testing: Selection of Reference Values and Interpretative Strategies. (1991). <http://www.thoracic.org/statements/>
10. Taussig, L.M., Wright, A.L., Holberg, C.J., Halonen, M., Morgan, W.J., and Martinez, F.D. (2003, April). Tucson Children's Respiratory Study: 1980 to present. *J Allergy Clin Immunol*, 111(4), 661-75.
11. Burney, P.G., Luczynska, C., Chinn, S., and Jarvis, D. (1994, May). The European Community Respiratory Health Survey. *Eur Respir J*, 7(5), 954-60.

12. Menezes, A.M., Victora, C.G., and Perez-Padilla, R. (2004, June). The PLATINO Team. The Platino project: methodology of a multicenter prevalence survey of chronic obstructive pulmonary disease in major Latin American cities. *BMC Med Res Methodol*, 17(4), 15.
13. NHLBI. The Framingham Heart Study. (2005). <http://www.nhlbi.nih.gov/about/framingham/index.html>
14. National Center for Health Statistics. <http://www.cdc.gov/nchs/fastats/deaths.htm>

2. EQUIPMENT AND SUPPLIES

The two subcomponents of Respiratory Health, ENO and Spirometry, are conducted in an examination room in trailer 1 of the MEC. The walls of the spirometry room are carpeted as a sound buffer for verbal coaching during spirometric testing. This chapter describes the spirometry equipment and supplies and explains the procedures for the setup, operation, and packup of the spirometry component.

2.1 List of Equipment and Supplies

All of the spirometry equipment meets the current ATS guidelines for accuracy and precision of diagnostic devices. A complete list of the equipment and supplies for this component is provided as follows:

Equipment

- Spirometer
- Calibration syringe
- Temperature/barometric monitor
- Spirometer hoses
- Stadiometer*
- Scale*
- Stool*
- Wastebasket
- Container for PFT kits
- Container for clean hoses

Supplies

- PFT kit (mouthpiece, nose clip, filter)
- Padded nose clips
- Cardboard mouthpieces
- Stopcock grease
- Germicidal wipes
- Nonlatex gloves
- Tissues*
- 9-Volt Batteries

*These items are shared with the ENO component; refer to the *ENO Procedures Manual*, Chapter 2.

At the beginning and end of each stand, the health technologist will inventory all component-specific equipment and supplies. Supplies ordered from the warehouse by the previous team should be on site when the next examination staff arrives at the MEC. Technologists will check all newly received supplies against the associated packing slips before incorporating them into the existing inventory. After reconciling the supplies, the technologist will stock the spirometry exam room and store additional supplies in the designated MEC belly compartment. Any needed items should be noted on the

inventory sheet, reported to the chief technologist and MEC manager, and documented in the Unusual Field Occurrence or UFO system (refer to *UFO Utility Manual* for details).

2.2 Description of Equipment and Supplies

2.2.1 Equipment

■ Spirometer

The spirometer is a device that measures the amount of air a subject exhales and the rate at which the air is exhaled. The present survey uses the Ohio 822/827 dry-rolling seal volume spirometer. Each MEC caravan will house one spirometer and the home office will retain a spare in the event of a malfunction in the field. NIOSH will also retain a fifth spirometer at the Morgantown laboratory. The same spirometers were also employed in the NHANES III data collection cycle (1988-1994). These devices have been reconditioned for use in the current survey and will be maintained by NIOSH technicians.

The Ohio 822/827 spirometer meets three basic requirements of NIOSH spirometer systems:

- (1) The system must be as accurate as possible using available technology;
- (2) The system must have sufficient backup to prevent loss of at least basic spirometric parameters; and
- (3) The system must be reliable for use in remote field locations where subject testing time is limited.

The spirometry system is also required to meet the NIOSH and American Thoracic Society's most recent Recommendations and Guidelines for the performance and interpretation of spirometry (5, 13, 19). For informational purposes, the basic design criteria for the NIOSH spirometry system are provided in Appendix A.

■ Calibration Syringe

A calibration syringe will be used to calibrate the spirometer prior to the start of every session. The syringe consists of a 3-liter metal cylinder with a rubber seal piston. The purpose of spirometer calibration with the syringe is to check the volume accuracy of the spirometer (see chapter 4, Quality Control, for detailed procedures).

- **Temperature/Barometric Monitor**

Barometric pressure and room temperature will be obtained using the Perception II Unit for Temperature/Barometric Pressure Measurement device along with the WeatherLink Software for Perception. The spirometry software system is designed to automatically capture the temperature and barometric pressure from the measurement device for each exam. The temperature is set in Celsius (C°) and the barometric pressure in millimeters of mercury (MM).

- **Spirometer Hoses**

The spirometer hose is a plastic, accordion-style breathing tube that attaches to the spirometer. Attached at the end of the hose is the plastic hose adapter. During spirometric testing the participant will exhale forcefully through the tube into the spirometer. Hoses will be changed on a daily basis and shipped to NIOSH for cleaning at the end of the stand.

- **Wastebasket**

A wastebasket will be kept in the exam room.

- **Container for PFT kits**

A plastic container will be available to hold unused PFT kits.

- **Container for clean hoses**

Spirometer hoses and hose adapters will be stored in a container. The clean hoses will be stored in the container labeled “clean hoses” and, once used, they will be stored in a plastic bag and stored in the MEC belly compartment.

2.2.2 Supplies

- **PFT kits**

The PFT kits consist of a filter, a cardboard mouthpiece, and a nose clip. Prior to performing spirometric testing, the technologist will insert a new filter into the hose adapter and ask the participant to insert the cardboard mouthpiece into the filter. The participant will be asked to wear a disposable nose clip during spirometric testing. After testing is completed, the technologist will remove and discard the used filter, mouthpiece, and nose clip in preparation for the next participant.

- **Padded Nose Clips**

Those who have difficulty with the nose clip from the PFT kits will be given the padded nose clip to wear. The nose clip ensures maximal exhalation through the spirotube and prevents the participant from inhaling additional air through the nose. Participants unable to keep a nose clip on their nose will have to pinch their nose with their fingers. Participants may discard the nose clip after the testing is completed.

- **Cardboard Mouthpieces**

Cardboard mouthpieces are provided in case a participant needs additional ones or for the technologist to use when demonstrating the maneuvers.

- **Stopcock Grease**

After cleaning and disinfecting the spirometer, the technologist will apply valve lubricant or stopcock grease on the rubber O-ring that fits in the groove of the spirometer snout plate. The technologist should lubricate the O-ring *lightly* with the stopcock grease.

IMPORTANT: Do not allow any lubricant on the metal snout plate itself (see Section 2.4).

- **Germicidal Wipes**

Disposable, germicidal wipes are used to clean and disinfect the spirometer, especially the inner cavity into which participants have exhaled. The technologist should wear gloves during this process (see Section 2.4).

- **Nonlatex Gloves**

A box of nonlatex gloves will be kept in the spirometry room for use by the technologist when cleaning/disinfecting spirometry equipment.

- **9-Volt Battery**

The battery will be used for the weather station.

2.3 Equipment Setup Procedures

The following procedures describe how to set up the spirometry equipment and supplies at the Start of a Stand.

2.3.1 Equipment

1. Turn computer on;
2. Remove the **spirometer** from its storage case;
3. Connect the computer cable labeled “comp port #1” to the spirometer cable labeled “comp port # 1”;
4. Connect the spirometer power cable to the UPS power supply receptacle;

5. Ensure that the computer is turned on. When the computer is completely booted up, connect the power to the spirometer. This sequence must always be followed in order for the spirometry software systems to work correctly. Not following this procedure may result in software malfunction.

NOTE: Allow 30 minutes for the spirometer and the calibration syringe to warm up before performing calibration checks or spirometric testing.

6. Remove the plastic cap from the opening to the spirometer and place in the storage case.
7. Remove a clean hose from the hose container and attach the **hose** to the spirometer. The clean hose box should be left in the exam room;
8. Remove the **calibration syringe** from its storage box and place the syringe near the spirometer.
9. Unpack the **temperature/barometer monitor** and console. Connect the computer cable labeled “comp port #3” to the monitor cable labeled “comp port #3.” Plug the power cord into the power outlet.
 - Install the battery by inserting the 9-volt battery into the monitor. Remove the battery cover underneath the unit by pressing on the back of the raised tab until the cover comes free. Snap the battery connector onto the battery. Lower the battery into the compartment. Replace the battery cover by placing it over the compartment and pressing down until the tab snaps into place. ***Please Note*** **When the unit is operating on battery power, the digits on the right side of the display blink on and off. The unit operates normally in all other respects.** Set the device in its console.
 - **The temperature should be set in Celsius (C°) and the barometric pressure in millimeters of mercury (MM).** To set the temperature at C°: press *TEMP*; then press *UNITS* until the C° unit appears on the right side of the display. Please note that the temperature measure is at F° or C°. To set the barometric pressure at MM: press *BAR* then press *UNITS* until the MM measure appears. The barometric pressure units are in IN, MM or MB.
10. Place the syringe box and barometer/temperature packing box in the spirometer case and store in the designated MEC belly compartment;
11. Ensure that the **container for storing PFT kits** is available in the spirometry room; and
12. Ensure that a **wastebasket** is available in the spirometry room.

2.3.2 Supplies

1. Fill the designated containers with **PFT kits** and make them accessible in the spirometry room;
2. Ensure that a box of **tissues** is available and accessible in the room; and
3. Check that the following spirometer cleaning and disinfectant supplies are available: **stopcock grease, germicidal wipes, and nonlatex gloves.**

2.4 Equipment Care and Maintenance

Follow the procedures below for the care and maintenance of the spirometer and hoses.

2.4.1 Spirometer

For infection control purposes, the spirometer *must* be cleaned and disinfected internally at the Start of Stand, Weekly, and End of Stand. On a daily basis, the technologist will also inspect the external surfaces of the spirometer and wipe clean with disinfectant wipes as needed.

To clean and disinfect the spirometer internally:

1. Remove the cap or hose from the spirometer opening;
NOTE: NEVER unhook the negator from the spirometer. If you reattach incorrectly or simply forget to reattach it, the next SP could pop the seal and it would require a **MAJOR** fix by NIOSH.
2. Remove the snout plate by rotating the three thumbscrews counterclockwise until the snout plate is free. Be sure to loosen the three screws evenly;
3. Carefully reach inside the cylinder and slowly push the piston back to expose the seal;
4. Using gloves, wipe the inside of the cylinder wall with germicidal disposable wipes;
NOTE: Do not use alcohol, acetone, other volatile agents or abrasive cleaners on the rolling seal.
8. Do not touch the rolling seal while cleaning the cylinder, as the seal can be easily damaged and might cause a leak;
9. Separate the rubber O-ring from the snout plate;

10. Clean the O-ring with germicidal disposable wipes;
11. Lubricate the O-ring lightly with stopcock grease and reinsert it into the groove on the back of the snout plate;

NOTE: Do not allow any lubricant on the metal snout plate.
12. Wipe the snout plate with a germicidal disposable wipe;
13. Be sure the interior of the spirometer is thoroughly dry. Gently pull the shaft of the piston from the rear of the spirometer several times to flush air through the spirometer;
14. When the inside of the spirometer is dry, replace the snout plate by positioning the plate so that the three thumbscrews are aligned with the three holes on the spirometer housing. Tighten the screws only “finger-tight,” alternating between screws to obtain a uniform tightening of the screws;

NOTE: Do not overtighten the snout plate screws.
15. Attach a clean hose to the spirometer opening; and

2.4.2 Hoses

For infection control purposes, hoses and hose adapters should be changed daily, at a minimum, and if the technologist notices water dripping from the end of the hose.

1. Place the used hose with its hose adapter in the plastic bag;
2. Take a clean hose with its hose adapter from the container labeled “clean hoses” and place it at the end of the spirometer.

2.5 Equipment Packup Procedures

At the End of the Stand, follow the procedures listed below to pack up the spirometry equipment for travel to the next stand.

2.5.1 Equipment

1. Retrieve the spirometry storage case from the MEC belly compartment;
2. Disconnect the spirometer power cable from the UPS power supply receptacle;
3. Disconnect the computer cable from the **spirometer**;
4. If not already done, detach the **hose** from the spirometer;
5. Replace the plastic cap on the opening to the spirometer;
6. Place the spirometer in the spirometer box;
7. Place all used and unused hoses with their hose adapters in the plastic container, seal it tightly, and ship to NIOSH for cleaning;
8. Insert the plug in the opening of the calibration syringe and pack the **calibration syringe** securely in its storage box;
9. Disconnect the **temperature/barometer monitor** cable from the computer and disconnect the power cord from the device. Do not take out the 9-volt battery, it should be in the monitor while it travels. Pack the device and console securely in its storage box;
10. Discard any trash into the **wastebasket**.

2.5.2 Supplies

1. Pack the following exam supplies in the storage container: **PFT kits, padded nose clips, cardboard mouthpieces, and tissues**.
2. Pack the following cleaning and disinfectant supplies in the MEC belly compartment: **stopcock grease, germicidal wipes, and nonlatex gloves**.

3. EXAMINATION PROTOCOL

The accuracy of the spirometry examination largely depends on the effort exerted by the examinee and the conscientiousness of the technologist. Consequently, it is crucial that the examination protocol be observed consistently and that the examinee be carefully prepared and “coached” for this examination. Insufficient effort on the part of the participants will produce test results that are inadequate both clinically and for the purposes of analysis.

Please note that Spirometry is part of the Respiratory Health component that includes both Spirometry and ENO. In this chapter, the spirometry examination protocol will be described. Please refer to the *ENO Procedures Manual* for the ENO test.

3.1 Eligibility Criteria for Spirometry and Bronchodilator Components

Examinees aged 6-79 years are eligible for the spirometry component. Examinees will be excluded from spirometric testing if they answer positively to any of the spirometry safety exclusion questions described in Section 3.2 and component safety exclusion questions described in Section 3.3 of the *ENO Procedures Manual*. Based on the initial spirometry results, a subgroup of participants will be asked to take a bronchodilator medication and repeat the lung function test. These participants will each be sent to the MEC physician, who will screen them for bronchodilator eligibility using a set of safety exclusion criteria (see *Bronchodilator Procedures Manual*). The physician will administer the bronchodilator medication to those found to be eligible. The participants will then return to the spirometry exam room where the technologist will repeat the lung function test.

3.2 Spirometry Safety Exclusion Questions

The spirometry safety exclusion questions will be asked during the ENO examination. Technicians will administer them while waiting for ENO trial #2 results. The questions will be administered to all age-eligible SPs (aged 6-79 years), with the exception of select questions that will be directed to participants aged 6-15 years or 16-79 years only. Parents of children 6-15 years will answer most of these questions prior to the exam, in most cases, so that responses will be completed and graded

out during the ENO waiting period. Table 3-1 summarizes the question items and applicable age ranges within each category.

Table 3-1. Spirometry safety exclusion items by age

Screening item by category	Age range eligibility (years)
Current painful ear infection	6-15
Eye surgery in the last 3 months	6-79
Chest/abdominal surgery in last 3 months	6-79
SP or household member tuberculosis exposure	6-79
History of aneurysm or collapsed lung	6-79
History of detached retina	16-79
Stroke or heart attack in the last 3 months	16-79
History of coughing up blood in last month	6-79

The safety exclusion questions of the instrument are listed below. To view the individual screenshots of each question, see Appendix B.

- SPQ.010 Does SP have a painful ear infection?
- SPQ.020 Have you ever had eye surgery? (Do not include cosmetic surgery on the eyelid or skin around the eye.)
- SPQ.030 Was the eye surgery in the last 3 months?
- SPQ.040 Have you ever had open chest or abdominal surgery?
- SPQ.050 Was the open chest or abdominal surgery in the last 3 months?
- SPQ.060 Did you or anyone in your household have tuberculosis in the past year?
- SPQ.070a Has a doctor or other health professional told you that you had an aneurysm?
- SPQ.070b Has a doctor or other health professional told you that you had a collapsed lung?
- SPQ.070c Has a doctor or other health professional told you that you had a detached retina?
- SPQ.070d Has a doctor or other health professional told you that you had a stroke?
- SPQ.070e Has a doctor or other health professional told you that you had a heart attack?
- SPQ.080 Did this stroke happen in the last 3 months?

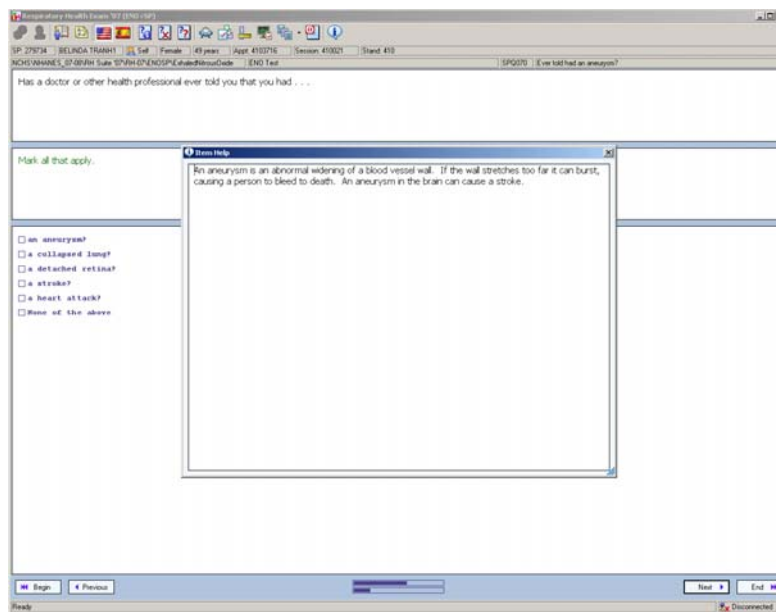
SPQ.090 Was your heart attack in the last 3 months?

SPQ.100 In the past month, have you coughed up blood?

Response options for this questionnaire are in the form of radio buttons for “Yes” and “No.” The toolbar menu at the top of the screen also contains response options for “Refused” and “Don’t Know.” If the technologist records a “Yes,” “Refused,” or “Don’t Know” response to any of the safety exclusion questions, the participant will be excluded from spirometry. However, if a “Yes” response is recorded for the questions concerning eye surgery (SPQ.020), open chest or abdominal surgery (SPQ.040), stroke (SPQ.070d), or heart attack (SPQ.070e), the technologist will ask whether the event occurred in the previous 3 months. Participants will be excluded from spirometry if they had eye surgery, open chest or abdominal surgery, stroke, or heart attack **specifically** in the past 3 months.

With regard to the aneurysm question (SPQ.070a), if the participant indicates that he or she does not know what an aneurysm is, click on the Help icon in the toolbar menu to access the following definition (Exhibit 3-1):

Exhibit 3-1. Aneurysm help screen



Spirometry examinations must not be performed on any excluded participants. When a participant becomes excluded, the application will prompt him or her to finish the ENO exam. It will then take you to the screen where it indicates that the participant is excluded from spirometry. See Exhibit 3-2. It will then automatically skip to the First Test: End of Subsection screen (Exhibit 3-3). For the spirometry component, the ISIS application will automatically fill in the radio button for “Not done.” In the Comment box “Safety Exclusion” will appear highlighted as the reason the exam was not performed.

Exhibit 3-2. Spirometry exclusion

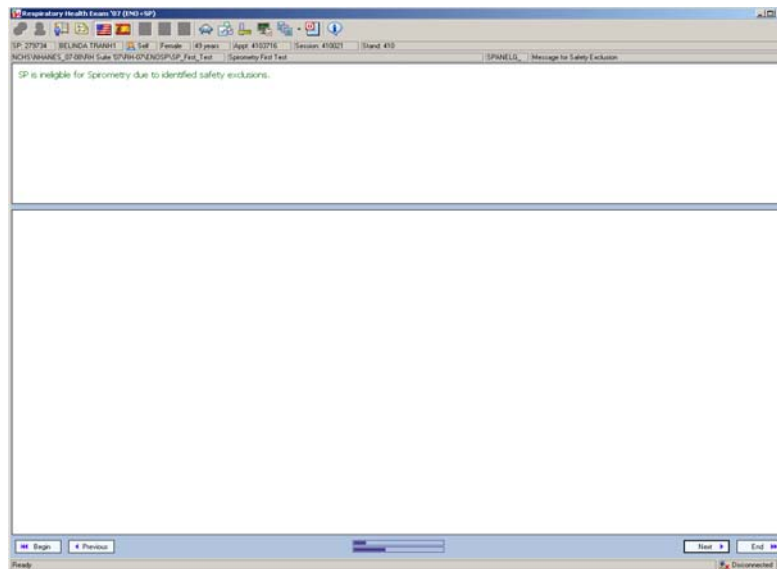
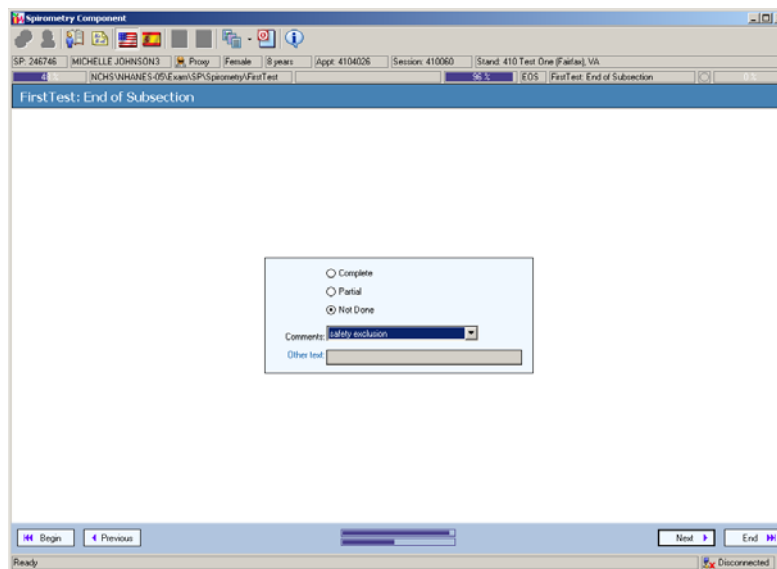
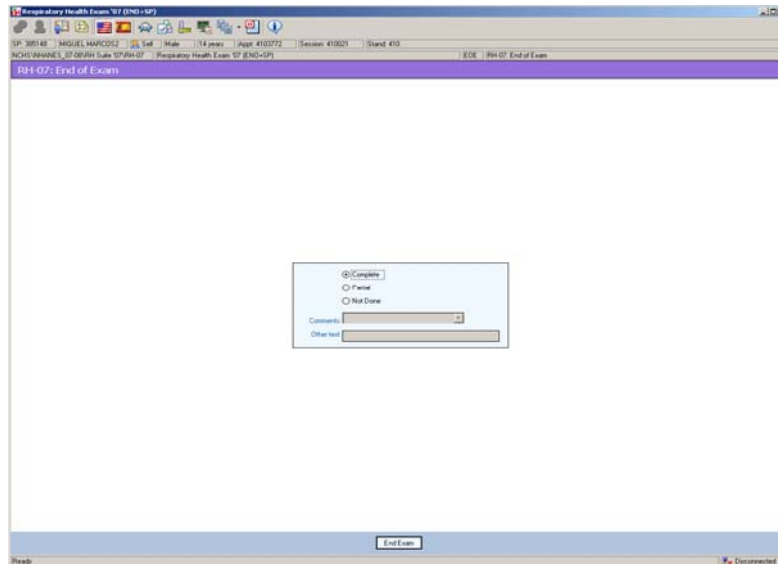


Exhibit 3-3. End of subsection screen



Alternatively, if the technologist records “No” to all of the safety exclusion questions, the application will proceed through the examination until the End of Subsection screen is reached. When the technologist clicks “Next” on the above screen, ISIS will advance to the final spirometry component screen entitled, SP: End of Exam (Exhibit 3-4).

Exhibit 3-4. End of exam screen



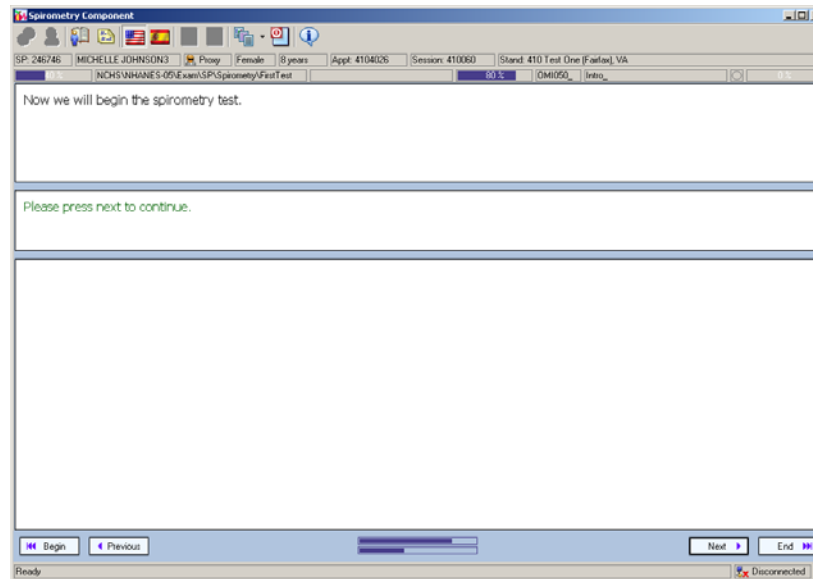
For excluded participants, the application will automatically label the exam status as “Not Done,” with a Comment of “Safety Exclusion” on both the End of Subsection and End of Exam screen. The spirometry component will then be concluded.

If the participant is *not* excluded from spirometry, ISIS will allow the technologist to proceed through the remaining safety exclusion questions and testing screens. At the end of the exam, the application will automatically mark the component exam status as “Complete” on the End of Subsection screen (pre-exam interview is completed) and, depending on the participant’s spirometry results, “Partial” (repeat spirometric testing is pending) or “Complete” (no repeat spirometric testing is necessary) on the End of Exam screen. Refer to Section 3.3.4 for more details.

3.3 Spirometry Examination Procedures

After the safety exclusion questions are completed, ISIS will present the following screen, Exhibit 3-5, prompting you to begin the spirometry test:

Exhibit 3-5. Begin spirometry test screen



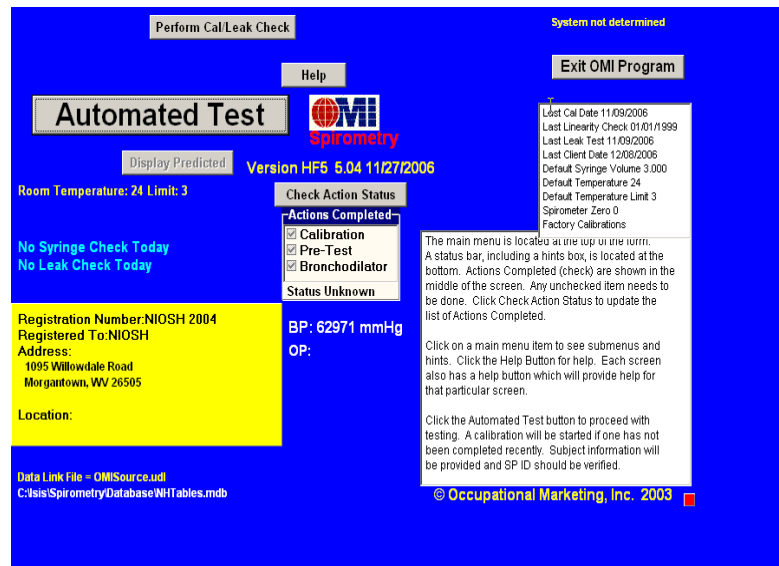
When this screen appears, click “Next.” ISIS will now transfer you to the OMI/NIOSH custom spirometry software that controls the testing portion of the spirometry component. ISIS will also automatically load the following demographic data into this software system in preparation for spirometric testing: SP identification number, age, gender, race/ethnicity, height, and weight.

NOTE: The OMI/NIOSH (Occupational Marketing Inc./National Institute for Occupational Safety and Health) software system was developed as a multipurpose software package adaptable for many different kinds of research studies. The NHANES 2007 spirometry study will use only selected features of this software system. **Please follow the instructions carefully and do not click on or enter sections of the software system that will not be used in the survey.** This could lead to data capture errors or corruption of the NHANES data files.

3.3.1 Spirometry Testing Procedures

On the OMI/NIOSH main screen (Exhibit 3-6), click on “Automated Test” to access the testing screens. Do not click on any other buttons at this time.

Exhibit 3-6. OMI/NIOSH main program screen



Verify the barometric pressure, type of test (pre-test, post-test and/or bronchodilator), your examiner initials, the spirometer temperature, and room temperature. The OMI/NIOSH software will compare the spirometer’s internal temperature to the room temperature and provide a warning message if there is more than a 3 degree difference. The screen shown below shows the warning message and a spirometer temperature of 99° C, the value that indicates a malfunction of the spirometer temperature sensor.

When you are ready to perform the trial or forced vital capacity test maneuver, click “Proceed with Testing” (Exhibit 3-7) to begin the spirometry test.

3.3.2 Instruction and Preparation

Follow the instructions below to prepare participants for spirometric testing.

1. Repeat the purpose of the examination and emphasize the need for extra effort from the participant to get maximal results.
2. Ask the participant to loosen any tight clothing and to remove dentures if they are not secure.

NOTE: Dentures will not need to be removed unless they interfere with spirometric testing.

Exhibit 3-7. Proceed with testing screen

OMI Spirometry Main Program - Version HF5 5.04 11/21/2006

Please verify and complete information below then click appropriate button below

Return to Main Screen Proceed with Testing Help

ReadOnly Items

Client ID: 385148

Last Name: *****

Last Session Number:

Session Number: 50

Spirometer Temperature: 24 C

Pre or Post Test

☒ Pre-Test

☐ Post-Test

☐ Bronchodilator

Hose ID:

Operator Initials: 1221

Barometric Pressure: 6297 mmHg

PFTSum The information below is provided for review purposes and cannot be edited with this screen

ID	Session	Test Date	Ht	Wt	Metric	Manual Entry	Smoker	Company
385148	50	12/08/2006 10:45:1		50	True	False		Not Listed

3. Open the PFT kit and place the filter onto the hose and install the cardboard mouth piece in the filter using the plastic wrap. Make certain that the cardboard mouthpiece is inserted into the filter firmly, so as to avoid air leaks in the system.
4. All NHANES spirometric testing should be performed in the standing position, unless the sample person is physically unable to do so. Therefore, ask the participant to stand during the examination but ensure that the stool is positioned behind the participant. If the SP cannot stand, seat him or her in a stool and proceed with testing. The software will ask you to record the participant's testing position (standing/sitting) after the first maneuver.
5. Have participant elevate the chin and extend the neck slightly. This is important because if the chin is down, it creates a partial airway obstruction. In this case, the spirogram for the participant may show a falsely positive obstructive pattern.

6. Have the participant hold the hose rather than the filter for testing. Holding onto the filter might cause the filter to become loose and cause a leak.
7. Have the participant place a nose clip on his or her nose. The nose clip should be removed between trials. If the participant cannot tolerate the nose clip, he or she should hold their nose during trials.
8. Demonstrate a trial exhalation using your own mouthpiece. The following coaching instructions may be helpful:

For Adults:

- “Take a big deep breath and fill your lungs with air.”
- “Put the mouthpiece into your mouth, between your teeth, and on top of your tongue. Lightly bite on the mouthpiece. Tightly seal your lips around it.”
- “Blast the air out as hard and fast as you can.”
- “Keep on blowing out the same breath of air, until I tell you to stop.”

For Children:

- “We want to see how your lungs work. We will measure how much air you can take in and how much you can blow out.”
- “Take in as much air as you possibly can.”
- “When you’re full, close your lips around the tube like this.”
- “Then blow out all of your air as fast and hard as you can. Keep blowing out hard until I tell you to stop.”

Allow the child one or two more practice trials in a relaxed fashion. If you are still unsure of the child’s understanding and ability to perform, demonstrate again (repeat the above steps), stressing anything that was not done properly. Reemphasize by exaggerated demonstration rather than words on how to do it correctly. Accent the positive; don’t say, “You did it wrong.”

9. **NOTE:** For ages 6-10 a minimum of 3 seconds of exhalation is recommended, whereas for ages 11-79 a minimum of 6 seconds of exhalation is recommended.
10. As the participant stops, direct him or her to hold the mouthpiece to the right side and away from his or her face, so that expired air from the spirometer does not blow back directly in the face.
11. Review the procedure and correct any problems from the trial. During subsequent testing, continue to coach the SP during each trial.

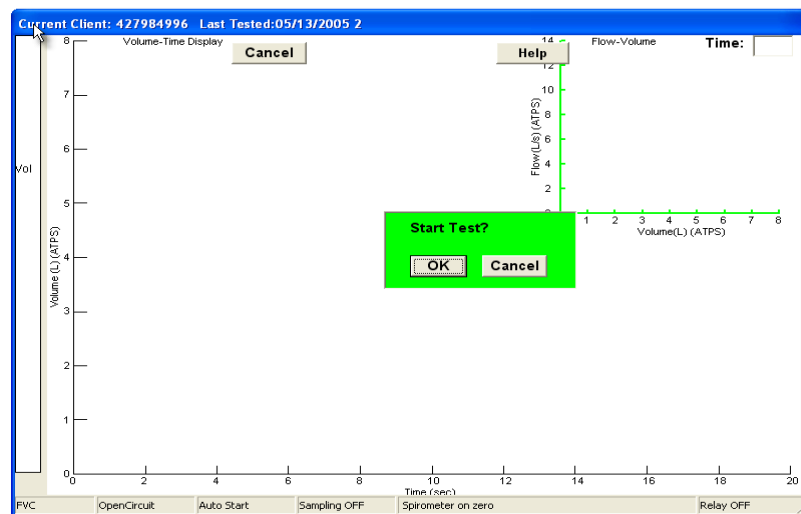
12. While coaching, make certain that you face towards the direction of the back wall of the spirometry room. This will have the effect of dampening the sound your voice makes and minimize the possibility of your voice being heard in other parts of the MEC.

IMPORTANT: Your attitude and encouragement will more likely evoke a good response from the SP than will formal instruction.

3.3.3 Initiate Test

When you are ready to initiate the test, click OK to the “Start Test?” window (Exhibit 3-8). A “Wait, Checking Spirometer” message will flash quickly in red on the screen. After the message disappears, instruct the participant to take a deep breath, insert the mouthpiece, and BLAST the air out!

Exhibit 3-8. Curve display screen – pre-test

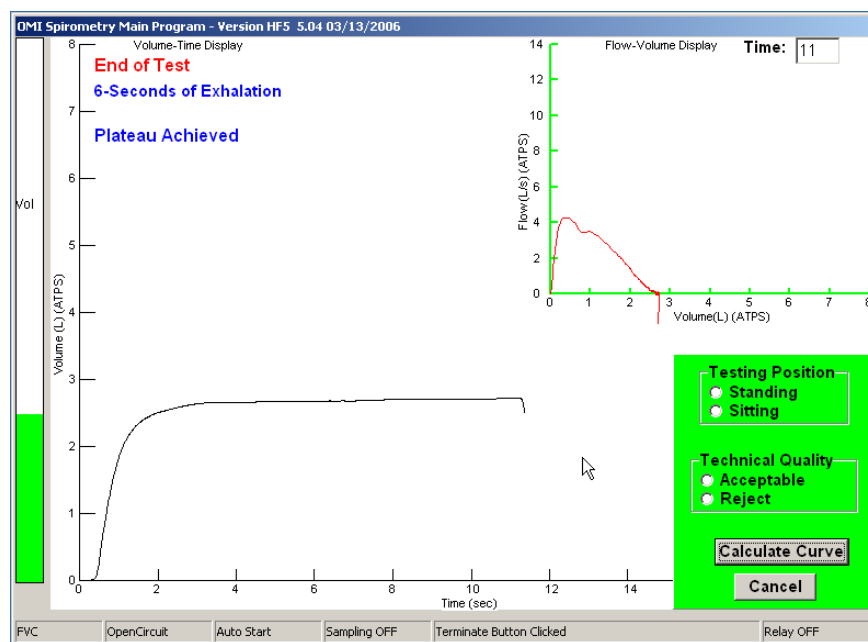


As you are continuing to coach the participant, it is important that you observe the participant continuously to make certain that there are no errors in technique. To ensure quality of testing, it is much more important to monitor the participant’s performance than to look at the computer screen. During an expiratory maneuver, the screen display should be looked at only very briefly and intermittently as necessary. Coach the participant to keep exhaling until the screen (Exhibit 3-9) displays two messages: “6 seconds of exhalation” (3 seconds in 6 to 10-year-olds); and “Plateau Achieved.”

The volume indicator bar on the left of the screen will change color from red to yellow with 6-seconds of exhalation; and to green when both a plateau and 6-seconds are achieved.

As soon as the messages “6-seconds of exhalation” and “Plateau Achieved” appear, instruct the participant to stop and remove the mouthpiece from the mouth. To reduce the risk of cross-contamination, remember to have the participant move the mouthpiece to the right side, away from the face, and away from the technologist.

Exhibit 3-9. Curve display screen

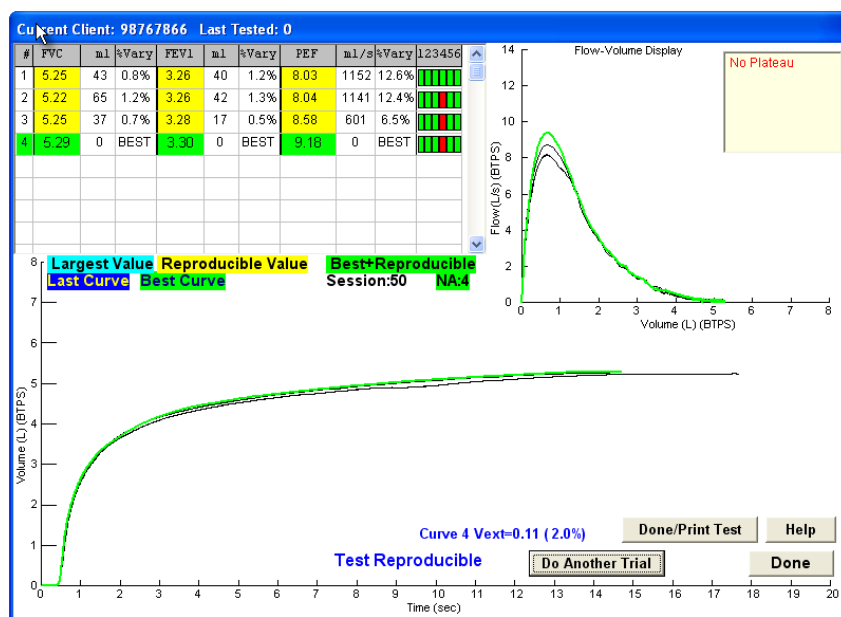


The “Testing Position” is defaulted to “Standing.” Click on “Technical Quality” either “Acceptable” or “Reject.” If you press “Calculate Curve” prior to selecting the technical quality, an error message will appear. When the “Calculate Curve” button is pressed, it will generate the test results. The Test Results screen (Exhibit 3-10) is displayed after each completed FVC maneuver. Before beginning another test, review the results according to the parameters outlined below. If another test is necessary, click on “Do Another Trial.” Please note that a maximum of eight tests will be conducted per SP. When you have finished testing the participant, i.e., no more than eight maneuvers, click “Done” to complete the testing portion of the spirometry component.

As shown above, the Test Results screen contains a table that includes the following: Trial Number, FVC, FEV1, and PEF. After the second and successive trials, the table will also calculate the differences from the largest observed values (expressed in milliliters and as a percentage).





Quality Code Box: The results table also contains a 6-item acceptability quality code box that is displayed to the right of the results for each trial. A more detailed view of the results table is shown in Exhibit 3-11. The largest values for FVC, FEV1, and PEF are indicated by “BEST” to the right of the value in the “% Vary” column. The milliliter differences and the percent differences between the individual values and the “best value” are also provided.

Exhibit 3-10. Test results screen



Recall that, for a spirometry test to be reproducible, the largest and second largest FVC must be within 150 ml of each other, and this must also be true of the FEV1. Therefore, the more FEV1 and FVC maneuvers that are within 150 ml of their respective “best” values, the more consistent is the effort. To obtain the best quality ratings, the largest and second largest FEV1 and the largest and second largest FVC must be reproducible within 100 ml. A scroll bar on the right can be used to scroll up or down to maneuvers not visible on the screen.

Exhibit 3-11. Results and quality code box

#	FVC	ml	%Vary	FEV1	ml	%Vary	PEF	ml/s	%Vary	123456
1	5.25	43	0.8%	3.26	40	1.2%	8.03	1152	12.6%	
2	5.22	65	1.2%	3.26	42	1.3%	8.04	1141	12.4%	
3	5.25	37	0.7%	3.28	17	0.5%	8.58	601	6.5%	
4	5.29	0	BEST	3.30	0	BEST	9.18	0	BEST	

In addition to the results table, all of the participants' flow-volume and volume-time curves are displayed superimposed on top of each other. The last maneuver is highlighted in blue and the best curve is green. All remaining curves are black. Any deleted or unusable curves (cough or large extrapolated volume) are red.

3.3.3.1 Acceptability and Reproducibility

Described below are the criteria for acceptable and reproducible curves.

Criteria for an acceptable spirogram:

- No hesitation or false starts on the part of the participant;
- Volume of back-extrapolation (Vext) less than 5% of the FVC or 0.15 L, whichever is greater;
- No coughing during the first second;
- No evidence of glottic closure, mouthpiece obstruction by tongue or dentures, or leaks;
- A visible plateau is present in the volume-time spirogram; and
- The exhaled breath maneuver should last at least 6 seconds.

Criteria for a reproducible spirogram:

- After **three** acceptable maneuvers, the **two** highest values for FVC and FEV1 (taken from acceptable forced expiratory maneuvers) must show minimal variability:
 - The two largest FVC values should agree within 150 ml, and
 - The two largest FEV1 values should agree within 150 ml.

Click on the quality code box (extreme right column), and a pop-up window is displayed allowing the user to override any acceptability code or reject a curve (Exhibit 3-12). The display screen provides the option for the Technician to reject a curve, but this should be used only in rare circumstances. This is because the OMI/NIOSH software will automatically evaluate the quality of each curve. Reject a curve only in circumstances where you believe that the software may not have recognized a defective curve—for example, the presence of a small progressive leak, or an undetected cough or extra breath being taken. Rejecting a curve omits that curve from further processing.

The same pop-up window also provides a legend of the acceptability codes. The reproducibility criteria are applied and a message is displayed on the Test Results screen (Exhibit 3-10 shown earlier) as to whether the test is reproducible. A green colored bar indicates the acceptability error is not present and a red bar indicates the error is present. Click on the Reject Curve button if you in fact wish to reject a curve, Set Cough button if you feel the computer did not correctly detect a cough, or Clear Cough button if you feel the computer incorrectly labeled the curve as having a cough. Any code that is “overridden” is colored blue instead of red. You may enter any comments concerning the curve in the Comments box at the bottom of the screen; however, normally you will leave this blank and enter overall test comments after the test is completed.

Exhibit 3-12. Override acceptability code screen

1	2	3	4	5	6
PEF Time	Low PEF	< 6 s	Plateau	Cough	Vext

Enter Curve Comments Below

Testing should continue until three acceptable tests (all green in the quality code box) and reproducibility criteria are met (yellow values), or until a maximum of eight tests have been performed, or until the participant cannot or should not continue. To obtain the highest quality rating, both the FEV1 and FVC reproducibility must be within 100 ml.

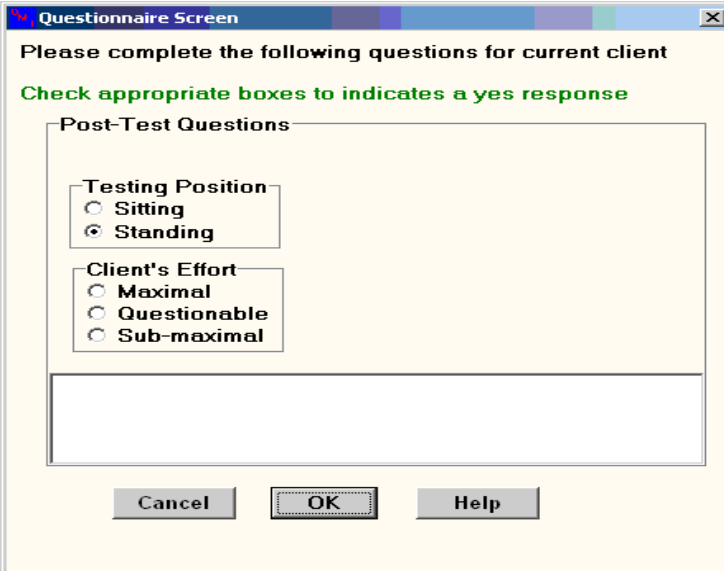
In summary, these quality assessment parameters are used to judge whether a curve is accepted or rejected. You do not need to reject a curve that is determined to be unacceptable (due to a cough or large extrapolated volume) by the computer as indicated by a red trial number and red curve. Prior curves may also be reassessed based on better curves that are achieved in subsequent trials. Ultimately, **the goal is to obtain green colored values for FVC, FEV1, and PEF, and a “Test Reproducible” message displayed at the bottom center of the screen.**

As previously stated, if another test is necessary, click on “Do Another Trial.” When you have completely finished testing the participant, i.e., no more than eight maneuvers, click “Done” to complete the testing portion of the spirometry component.

3.3.4 End of Test

After testing is completed, the “Post-Test Data” screen (Exhibit 3-13) will appear. On this screen the testing position will be prefilled with the position of the last individual test that was performed. Rate your impression of the effort exerted by the participant (maximal, questionable, or submaximal). A text box is also available for any comments regarding the participant’s spirometry test, e.g., participant’s cooperation, language-communication problems, mouthpiece leak, false start, early termination of expiration, etc.

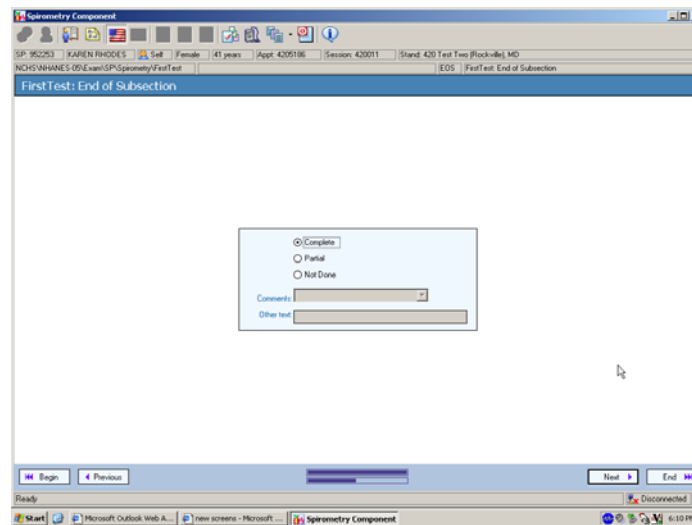
Exhibit 3-13. Post-Test data screen

The image shows a software window titled "Questionnaire Screen" with a standard Windows-style title bar (minimize, maximize, close buttons). The main content area has a yellow background and contains the following text: "Please complete the following questions for current client" in bold black font, followed by "Check appropriate boxes to indicates a yes response" in green font. Below this is a section titled "Post-Test Questions" in bold black font. Inside this section, there are two groups of radio buttons. The first group is labeled "Testing Position" and contains two options: "Sitting" (unselected) and "Standing" (selected with a black dot). The second group is labeled "Client's Effort" and contains three options: "Maximal" (unselected), "Questionable" (unselected), and "Sub-maximal" (unselected). Below these radio button groups is a large, empty white rectangular text box for comments. At the bottom of the window, there are three buttons: "Cancel", "OK", and "Help". The "OK" button is highlighted with a dashed border.

After completing the Post-Test Data screen, click “OK” to return to the OMI/NIOSH main screen. Click the “X” in the upper right corner of the main screen to exit the OMI/NIOSH software and return to the ISIS spirometry component application.

At this time, ask the participant to remove the filter and cardboard mouthpiece from the hose and discard them in the wastebasket. Click “Next” to advance to the End of Subsection screen (Exhibit 3-14).

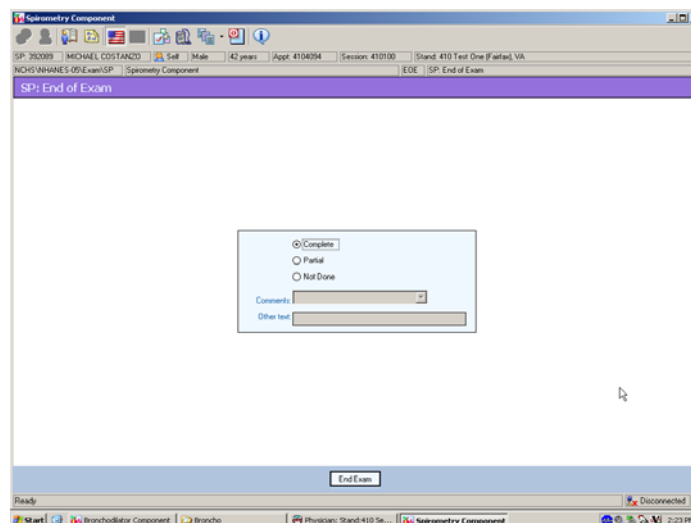
Exhibit 3-14. End of subsection – complete screen



The ISIS software will evaluate the participant’s spirometric test performance against normal reference standards that are predicted based on the participant’s age, sex, weight, height, and race/ethnicity. If the participant’s results fall within the normal range, then the spirometry component is concluded. In this case the next and final screen will be the End of Exam screen showing the status marked “Complete” (Exhibit 3-15).

The purpose of this screen is to document the overall status of the baseline spirometry examination: Complete, Partial, or Not Done. As with all other MEC exam components, ISIS will automatically fill in the applicable component status for each exam. For Partial and Not Done exams, select the appropriate reason using the drop-down menu of the Comments field, or choose Other, Specify and enter a brief explanation for the Partial or Not Done status.

Exhibit 3-15. End of exam screen



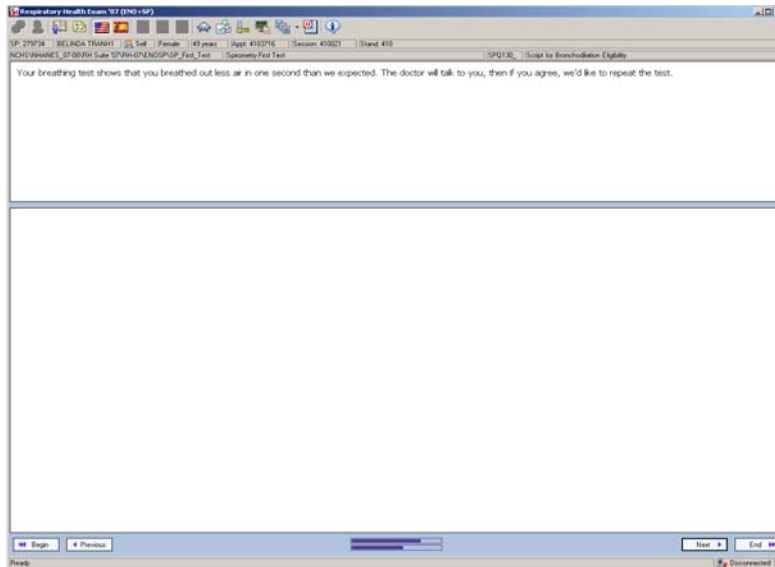
3.3.5 Procedures for Repeat Spirometry Testing

As mentioned above, at the end of the spirometry examination the ISIS software will evaluate the participant's spirometric test performance against predicted standards based on the participant's age, gender, race/ethnicity, height, and weight. Participants will qualify for the bronchodilator component if their baseline spirometry results meet the following criteria (see also Chapter 1, Section 1.6):

- $FEV_1/FVC\%$ less than the Lower Limit of Normal (LLN) determined for his or her age, sex, weight, height, and race/ethnicity, or
- $FEV_1/FVC\%$ less than 70 percent.

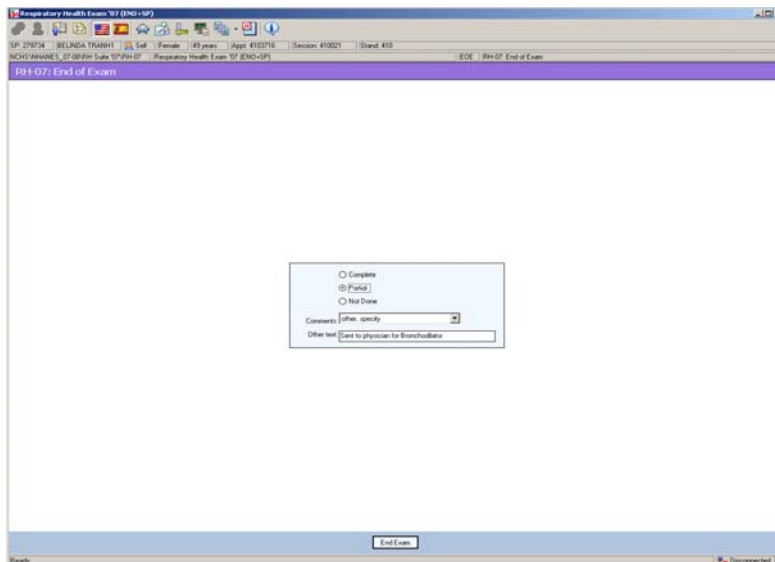
For these participants, ISIS will display a standard bronchodilator referral script for the technologist to read to them (Exhibit 3-16).

Exhibit 3-16. Technologist bronchodilator referral script screen



ISIS will then advance to the spirometry End of Exam screen (Exhibit 3-17) with the status marked “Partial.” The Comment box will indicate that the participant will be sent to the physician for the bronchodilator component (see *Bronchodilator Component Procedures Manual* for details).

Exhibit 3-17. End of exam – SP to bronchodilator screen



Regarding participants who meet the bronchodilator criteria, the MEC coordinator will assign them to the bronchodilator component located in the physician’s room. Here the physician will

screen them to determine their eligibility to take the bronchodilator medication (*see Bronchodilator Procedures Manual* for details). Participants who ultimately receive the medication will then be reassigned to the spirometry component following a 10-minute wait time while the medication takes effect. The coordinator software application is designed to block reassignment of these participants to spirometry until the 10 minutes have transpired. When the participant returns to the spirometry room, the technologist will repeat spirometric testing using the same procedures explained in section 3.3. The only difference between the baseline and repeat spirometry examination is that the repeat exam will not include the pre-examination questions.

Finally, there are some participants whose spirometry results exhibit a FEV₁/FVC% less than 50 percent of that predicted based on their demographic characteristics, which indicates a likelihood of having severe obstructive lung disease. The ISIS software is designed to automatically require these participants to visit the physician, who will assess whether referral to a community provider is necessary. Thus, at the end of the spirometry component, ISIS will display the script for the technologist to inform the participant.

3.4 Troubleshooting Spirometry Examinations

Report all spirometry equipment malfunctions promptly to the chief technologist, MEC manager, and Westat component specialist. If the issue is computer-related and cannot be resolved by the chief technologist and/or MEC manager, contact the home office ISIS support staff for assistance. Document the issue documented in the Unusual Field Occurrence (UFO) system and/or Equipment Tracking System (ETS) system as appropriate (refer to the *UFO Utility Manual* and *ETS User Guide* for details).

Carefully pull back on the piston at back of the spirometer and hold your hand over the opening of the spirometer. If the counts do not stay stable, check the snout plate and O ring. Do the same maneuver. If the counts now are not stable, the hose has a leak; discard it.

Follow the troubleshooting procedures listed below if you suspect a leak during the spirometry examination. The leak checks should be conducted without a syringe.

1. Reinstruct the participant on the seal around the mouthpiece and do another test trial.

2. If you still suspect a leak, perform a leak test **without** a hose:
 - In the toolbar at the top of the OMI/NIOSH software screen, under the “Calibration” menu, select “Leak Test.”
 - Remove the hose from the spirometer
 - Carefully pull back on the piston.
 - Plug the cap at the end of the spirometer opening.
 - Click “OK.”
 - Note the “Current Volume” displayed on the screen: If the number goes down, this indicates a leak.
 - Click on “Start Timing” – A timer will count down 60 seconds.
 - If the leak volume is acceptable, the screen will read “Pass.”
 - Click “Save.”
3. If the results still fail, check the tightness of the snout plate screws. The likely cause is the O ring inside the channel on the back of the snout plate. Remove the snout plate, check the O ring, and lubricate the ring with silicone. If necessary, loosen or tighten screws so that they are all equally “thumb-tight.” If some screws are tighter or looser than others, this can lead to leak problems.
4. Perform the same maneuver described above.
5. If the counts don’t change, **add** the spirometer hose and conduct a leak check.
 - In the toolbar at the top of the OMI/NIOSH software screen, under the “Calibration” menu, select “Leak Test.”
 - Add only the hose with its adapter to the spirometer (no filter)
 - Carefully pull back on the piston.
 - Plug the hose cap at the end of the hose adapter.
 - Click “OK.”
 - Click on “Start Timing” – A timer will count down 60 seconds.
 - Note the “Current Volume” displayed on the screen: If the number goes down, this indicates a leak.
 - If the counts now are not stable, the hose has a leak; discard the hose.

6. If the counts are still stable then **add** the filter.
 - In the toolbar at the top of the OMI/NIOSH software screen, under the Calibration” menu, select “Leak Test.”
 - Add a new filter to the end of the hose adapter.
 - Carefully pull back on the piston.
 - Place your hand at the end of the filter.
 - Click “OK.”
 - Click on “Start Timing” – A timer will count down 60 seconds.
 - Note the “Current Volume” displayed on the screen: If the number goes down, this indicates a leak
7. If the count stays stable, then there is no leak. If the counts change only after adding the filter, then the filter is the leak source and discard it.
8. If the results fail after following the above procedures, document the failed calibration and/or leak check in the Unusual Field Occurrence (UFO) system and notify the chief technologist. The Westat component specialist will alert the NCHS Project Officer and contact the appropriate NIOSH representative for further assistance.

3.5 Report of Findings

Participants may ask how they did on this test. Inform them that the Spirometry test results will be sent to the National Institute for Occupational Safety and Health (NIOSH) for analysis. Participants will not receive any report of findings on the day of the exam but the results will be mailed home as part of the report of findings.

4. QUALITY CONTROL

Quality control procedures ensure the accurate and reliable collection and documentation of data. Please note that Spirometry is part of the Respiratory Health component that includes both ENO and Spirometry. In this chapter, quality control procedures for the Spirometry component are described. To view ENO quality control procedures, please refer to Chapter 4 of the *ENO Procedures Manual*.

4.1 Equipment Cleaning and Calibration

Routine cleaning and calibration of the spirometry equipment are essential quality control measures in order to ensure that the equipment produces accurate results. Specifically, the spirometer and hoses must be cleaned and disinfected, and the spirometer must be calibrated and checked for leaks according to the schedule outlined in this section. The technologist will complete these procedures using the spirometry Quality Control Checks dialog box that contains designated tabs for the Start of Stand, Daily, Start of Session, Weekly, and End of Stand. To access this dialog box, select the Quality Control Checks option from the toolbar menu at the top of the screen. Click the “Done” box beside each of the check items listed to record completion of the procedure.

4.1.1 Quality Control Checks Screens

The schedule for equipment cleaning and calibrations is provided in the following screens of the Quality Control Checks dialog box.

- **Start of Stand (Exhibit 4-1)**
 - SPIRO: Clean/disinfect spirometer, and
 - SPIRO: Calibrate spirometer/perform leak check with syringe.
 - Calibrate scale – Full
 - Calibrate stadiometer

Exhibit 4-1. Quality Control Checks – Start of Stand QC

QC Check	D	Result	Comment
SPIRO: Clean/disinfect spirometer.	<input type="checkbox"/>		
SPIRO: Calibrate spirometer/perform leak check with syringe.	<input type="checkbox"/>		
END: Label Stand # and date on a new blue card and insert card in device.	<input type="checkbox"/>		
END: Label Stand # and date on a new orange card.	<input type="checkbox"/>		
Calibrate scale - Full	<input type="checkbox"/>		
Calibrate stadiometer	<input type="checkbox"/>		
END: Enter ambient air - backup machine.	<input type="checkbox"/>		

Ok Cancel

■ **Daily (Exhibit 4-2)**

- SPIRO: Change hose

Exhibit 4-2. Quality Control Checks – Daily QC

QC Check	D	Result	Comment
SPIRO: Change hose.	<input type="checkbox"/>		
END: Enter ambient air NO in the result field.	<input type="checkbox"/>		
END: Enter # of measurements displayed on ENO machine. - MUST CHANGE SENSOR AT OR BEFORE 30 MEASUREMENTS.	<input type="checkbox"/>		

Ok Cancel

- **SPIRO:** Calibrate spirometer/perform leak check with syringe

Exhibit 4-3. Quality Control Checks – Start of Session QC

Quality Control Checks

Start of stand QC Daily QC **Start of session QC** Weekly QC End of stand QC

QC Check	D	Result	Comment
SPIRO: Calibrate spirometer/perform leak check with syringe.	<input type="checkbox"/>		

Ok Cancel

■ **Weekly (Exhibit 4-4)**

- SPIRO: Clean/disinfect spirometer
- SPIRO: Conduct weather check

Exhibit 4-4. Quality Control Checks – Weekly QC

Quality Control Checks

Start of stand QC Daily QC Start of session QC **Weekly QC** End of stand QC

QC Check	D	Result	Comment
SPIRO: Clean/disinfect spirometer.	<input type="checkbox"/>		
ENO: Wipe ENO device with alcohol prep.	<input type="checkbox"/>		
ENO: Enter 15 ppb QC sensor reading.	<input type="checkbox"/>		
ENO: Enter 75 ppb QC sensor reading.	<input type="checkbox"/>		
ENO: Enter QC filter reading.	<input type="checkbox"/>		
SPIRO: Conduct weather check.	<input type="checkbox"/>		

Ok Cancel

■ **End of Stand (Exhibit 4-5)**

- SPIRO: Clean/disinfect spirometer
- SPIRO: Ship used hoses and hose adapters to NIOSH

Exhibit 4-5. Quality Control Checks – End of Stand QC

QC Check	D	Result	Comment
SPIRO: Clean/disinfect spirometer.	<input type="checkbox"/>		
SPIRO: Ship used hoses and hose adapters to NIOSH.	<input type="checkbox"/>		
END: Ship used blue and orange test cards to Westat.	<input type="checkbox"/>		
END: Ship all sensors to Westat.	<input type="checkbox"/>		

When finished completing the required Quality Control Checks, click “OK” to exit the dialog box and return to the main spirometry component screen. However, if you have not checked the “Done” box beside all of the required checks, clicking “OK” will open the following pop-up window (Exhibit 4-6).

Exhibit 4-6. Quality Control Checks – Not Done QC

QC Check	D	Result	Comment
SPIRO: Clean/disinfect spirometer.	<input checked="" type="checkbox"/>	12/8/2006 11:16 AM	
SPIRO: Calibrate spirometer/perform leak check with syringe.	<input type="checkbox"/>		
END: Label Stand # and date on a new blue card and insert card in device.	<input type="checkbox"/>		
END: Label Stand # and date on a new orange card.	<input type="checkbox"/>		

To return to the QC Checks dialog box and complete the remaining checks, click “Cancel.” Alternatively, if you need to close out of the dialog box without completing all of the checks at this time, click “OK” to the above window to return to the main spirometry component screen.

4.1.2 Equipment Cleaning

For infection control purposes, the spirometer must be cleaned and disinfected internally at the Start of Stand, Weekly, and End of Stand. On a daily basis, the technologist will also inspect the external surfaces of the spirometer and wipe clean with disinfectant wipes as needed. Refer to Chapter 2, Equipment, Section 2.4, entitled Equipment Care and Maintenance for the procedures used to clean and disinfect the spirometer.

Hoses and hose adapters used during a day will be changed daily. Used hoses and adapters will be stored in a plastic bag and placed in the belly compartment. At the end of the stand, all hoses (used or not used), will be placed in the clear container where the clean hoses were stored, sealed, and shipped to NIOSH for cleaning. Any hoses that have a leak will be thrown away.

4.1.3 Equipment Calibration

Calibration of the spirometer includes a leak check and is performed using a standard three-liter calibration syringe. Spirometer calibration will be conducted at the Start of Stand and prior to the Start of Session. All calibration checks will be conducted using a new filter.

- The procedures for performing the spirometer calibration and leak check are outlined below:
 1. In the Quality Control Checks screen under the appropriate tab (i.e., Start of Stand or Start of Session), click the “D” box beside “Calibrate spirometer/perform leak check with syringe.” This will launch the OMI/NIOSH software system.
 2. On the OMI/NIOSH main menu screen, click the “Perform Cal/Leak Check” button.
 3. Fully withdraw the calibration syringe handle to its end position to completely fill the syringe with room air.

4. Place a new filter on a spirometer hose adapter and connect this to the opening of the calibration syringe. Then attach the calibration syringe with filter and adapter to the receiving fitting of the spirometer. Note that the receiving fitting of the spirometer has two rubber “O” rings inside. The fitting end of the calibration syringe unit must slide past both these “O” rings in order to achieve an airtight seal.

NOTE: Manually hold up the free end of the syringe so that it is level at all times while it is connected to the spirometer.

5. On the Syringe Calibration/Leak Check Routine window, click “OK” to open the calibration volume-time graph screen.
6. Click “OK” on the “Syringe Connected” window.

The following message will appear in red: “Empty syringe into the spirometer.”

7. Slowly and steadily push the syringe handle all the way in to empty the air contained in the syringe into the spirometer; at the same time continue to hold up the free end of the syringe while it is connected to the spirometer.

NOTE: Do not push the calibration syringe rapidly or forcefully as this may result in calibration difficulties or mechanical problems.

The spirometer system is designed to conduct the following two tests or checks:

Calibration Check: The software immediately and automatically compares the known syringe volume (3 liters) to the volume measured by the spirometer.

Leak Check: The software requires 60 seconds (1 minute) to check the volume of air that is leaked to the outside. Therefore, you must continue to hold the syringe in position and wait 60 seconds while the software completes the calibration and leak check cycle.

8. For the system to pass the calibration check, the volume of air measured by the spirometer must have accuracy within ± 3.5 percent (allows 0.5% for syringe accuracy) or ± 50 ml of the 3 liter calibration syringe volume, whichever is greater. The acceptable range for air measured by the spirometer during calibration is 2.9-3.1 liters.

For the system to pass the leak check, the total amount of air leaked over a 60-second period should not exceed 40 ml.

When the calibration and leak checks are completed, the Syringe Calibration Check Routine window will display the results and the following messages:

“Cal Pass” if the spirometer calibration check passed, and

“Leak Volume Pass” if the leak check passed.

9. If both the calibration and leak tests are passed, click “Save” on the Syringe Calibration Leak Check Routine window to store the results in the OMI/NIOSH calibration database. Please make certain to select these options when finished with calibration/leak testing. If you fail to select them, then the calibration data will not be stored in the computer system, and calibration will have to be repeated.
 10. To exit the OMI/NIOSH software, click the “X” in the top right corner of the main menu screen. Click “OK” to the window that immediately appears; it will state when the calibration check and leak test were last performed. This will then return you to the spirometry QC Checks dialog box.
- If the spirometer fails the calibration check or leak check, execute the following procedures:
 1. Repeat the calibration and leak check procedures listed above.

IMPORTANT:

- Ensure that the calibration syringe is both level and snugly attached to the filter and hose adapter. If not, this may result in leak test failure.
 - Make certain that the spirometer has no air inside of it before beginning the calibration test. The software will automatically add the volume of any residual air that remains present at the start of a test to the calibration syringe volume. This could potentially result in high measured calibration volumes that are unacceptable for quality control purposes.
 - Make certain that both the spirometer and the calibration syringe are at the same temperature before performing calibration checks. Gas volumes are temperature dependent; cold especially will significantly reduce measured gas volumes. Hence if the calibration syringe is stored in a different location from the spirometer, the temperature difference could cause a volume calibration check failure. These temperature differentials are a common cause of volume calibration check failures.
2. If the results still fail, check the tightness of the snout plate screws. The likely cause is the O ring inside the channel on the back of the snout plate. Remove the snout plate, check the O ring, and lubricate the ring with silicone.
 3. If necessary, loosen or tighten screws so that they are all equally “thumb-tight.” If some screws are tighter or looser than others, this can lead to leak problems.
 4. Repeat the spirometer calibration and leak check with the syringe.

5. If the counts don't change add the spirometer hose. Do the same maneuver. If the counts now are not stable, the hose has a leak; discard it. If the counts are still stable then add the filter. If the count stays stable then there is no leak. If the counts change only after adding the filter then the filter is the leak source and discard it.
6. If the results fail after following the above procedures, document the failed calibration and/or leak check in the Unusual Field Occurrence (UFO) system and notify the chief technologist. The Westat component specialist will alert the NCHS project officer and contact the appropriate NIOSH representative for further assistance.

4.2 Equipment Maintenance

Each MEC will be furnished with one spirometer and a syringe. A backup spirometer will also be kept at the home office for training and software testing purposes. In addition to the routine calibrations performed in the field by the technologist, NIOSH will calibrate each spirometer at the commencement of the survey and every 6 months thereafter. The Westat component specialist will coordinate the semiannual NIOSH calibrations with the survey schedule so as not to interfere with ongoing data collection activities.

If a spirometer in the field becomes disabled, document the problem in the UFO system and contact the chief technologist, MEC manager, and Westat component specialist immediately. Westat will arrange to send the backup spirometer to the field by overnight delivery. The component specialist will also coordinate with the MEC team to send the malfunctioning spirometer to NIOSH for repair.

4.3 Review of Results During the Exam

The OMI/NIOSH software is designed to visually assist the technologist in two major aspects of quality control in spirometric testing:

- Determination of the best coaching instructions to provide to the participant, and
- Judgment of whether three acceptable test trials have been achieved with the two highest FVC and FEV1 results showing minimal variability.

The procedures for reviewing spirometric testing results are fully explained in Chapter 3, Examination Protocol.

4.4 Observation

Staff from Westat, NCHS, and NIOSH will observe the spirometry and bronchodilator components at regular intervals. These observations will serve to verify that the protocol is being implemented correctly and consistently and that standard procedures and techniques are being followed. Problems or deviations will be noted and feedback will be provided to the technologists as necessary.

4.5 Review of Exam Status

To further monitor the quality of data collection, component staff will generate reports from the ISIS intraweb. The number of spirometry examinations and examination times: cumulative and sorted by session, by age group, and by technician, as well as the reasons for not done and partial examinations, will be monitored by stand.

4.6 Review of Results During Analysis

NCHS will generate a report of findings for each participant and send the report to the participant's mailing address.

In addition to analyzing the participant results, the designated NIOSH graders will review the data for technologist performance, assess the equipment calibration data for instrument performance, and direct recommendations for improvement to the appropriate personnel at NCHS and Westat. The Westat component specialist will provide feedback and additional training to the technologists as necessary. The next section describes the types of reports that will be generated and reviewed at NIOSH.

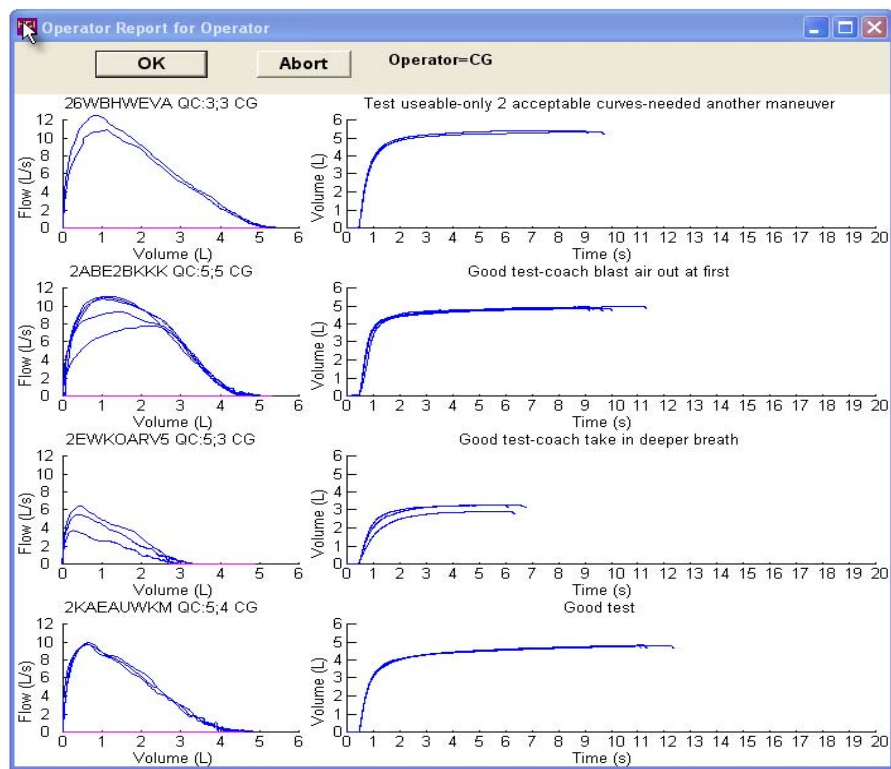
4.7 NIOSH Quality Control Reports

The following describes the types of quality control reports that the NIOSH graders will produce over the course of the spirometry data collection period.

4.7.1 Operator Reports

After reviewing each incoming batch of spirometry data, NIOSH will immediately notify NCHS/Westat of any serious errors concerning the calibration or examination procedures. Notification will take place in the form of an “Operator Report” sent via email to the appropriate Westat and NCHS staff. The Operator Report (Exhibit 4-7) will consist of a password protected .pdf file containing copies of all tests performed by a particular technician, including flow-volume, volume-time curves, FVC and FEV1 quality factor codes, and specific comments.

Exhibit 4-7. Operator Report



4.7.2 Statistics

At the end of the stand, NIOSH will also compile the following statistics for each technologist:

- Average number of acceptable maneuvers by technologist;
- Percentage of SPs with nonrepeatable tests results by technologist;
- Percentage of SPs with less than three acceptable maneuvers by technologist;
- Percentage of SPs with less than two acceptable maneuvers by technologist;
- Average FVC quality score by technologist; and
- Average FEV1 quality score by technologist.

4.7.3 Grades

NIOSH will also assign five letter grades (A, B, C, D, and F) to the spirometry results obtained by each technologist. The criteria for each grade are specified as follows:

- A – 3-acceptable curves, plus largest and second largest value within 100 ml, plus largest value not derived from last maneuver by more than 50 ml.
- B – 3-acceptable curves, plus largest and second largest value within 150 ml, equivalent to minimum American Thoracic Society's acceptability and repeatability criteria.
- C – 2-acceptable curves, plus largest and second largest value within 250 ml.
- D – 1 acceptable curve.
- F – No acceptable curves.

4.7.4 Summary and Trend Analysis Reports

NIOSH will incorporate the information compiled for the operator reports, statistics, and grades into a Quality Control Summary Report and a Calibration Summary Report. These reports will be

generated for individual technologists and for all technologists combined. Sample Summary Reports are provided for reference in Exhibits 4-8 and 4-9.

Exhibit 4-8. Quality Control Summary Report

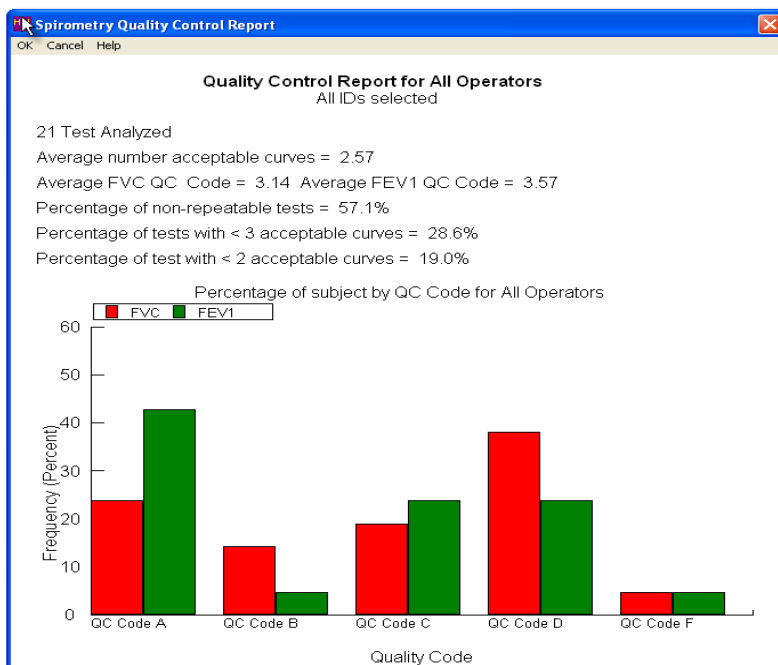
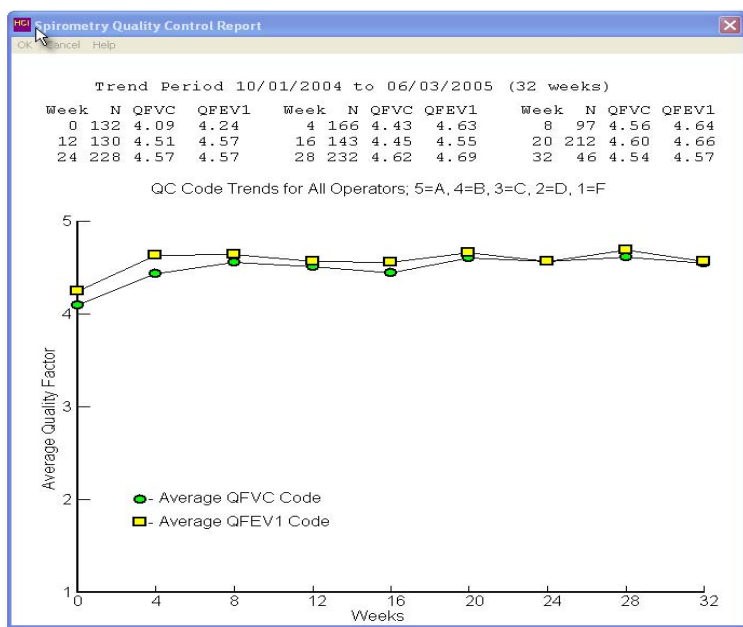


Exhibit 4-9. Calibration Summary Report

Spirimetry Quality Control Report				
OK Cancel Help				
Calibration Summary				
All IDs selected				
0 calibration checks, 0 leak checks				
No syringe calibration check errors				
No leak check errors				
Quality Control Summary Report By Operator				
All IDs selected				
Operators	Number	NA	QC(FVC)	QC(FEV1)
All Operators	21	0.54	3.14	3.57
	3	0.00	3.33	3.67
BB	13	0.87	3.46	4.00
JLH	2	0.00	2.50	2.50
KZK	2	0.00	2.00	2.00
MY	1	0.00	2.00	3.00

NIOSH will also monitor trends of the average FVC and FEV1 results over the course of data collection. Exhibit 4-10 shows a sample Trend Analysis Report for all technologists combined.

Exhibit 4-10. Trend Analysis Report



Based on a review of these reports, NIOSH will notify the appropriate NCHS project officer and Westat component specialist when specific quality issues need to be addressed. In response, Westat will arrange to provide feedback and additional training to the technologists.

5. SAFETY PROCEDURES

5.1 Spirometry Safety Precautions

The major safety precautions taken in the spirometry component are screening participants for medical conditions that make spirometric testing unsafe, prevention of electrical shock during the procedure, and prevention of infection transmission among participants and exam staff.

5.1.1 Safety Exclusion Screening

The majority of the baseline safety exclusion question consists of questions designed to exclude participants from spirometric testing for safety reasons. See Chapter 3, Examination Protocol, Section 3.2, for a complete list of the safety exclusion questions for baseline spirometry testing. A few of the safety exclusion questionnaire items apply only to certain age groups.

Participants who qualify for the bronchodilator component will receive a safety exclusion evaluation by the MEC physician. Only those SPs whom the physician determines to be eligible for the bronchodilator will receive the medication. Refer to the *Bronchodilator Component Procedures Manual* for details.

5.1.2 Infection Control Measures

The transmission of infections between SPs, or from the SP to the technologist, is a remote possibility. Specifically, lung function equipment has not been directly implicated in the transmission of infections.* Regardless, the following measures are taken to minimize the least risk of infection transmission among SPs and MEC staff:

- The spirometry baseline screening questionnaire includes exclusion questions about exposure to tuberculosis. Specifically, those who have been diagnosed and treated for tuberculosis, or whose household members have been diagnosed with tuberculosis, will be excluded from spirometric testing. Also excluded are participants with a

* Miller, M.R., Crapo, R., and Hankinson, J. et. al., (2005, July). General considerations for lung function testing. *Eur Respir J.*, 26(1):153-61.

history of coughing up blood (hemoptysis) in the last month, which can be a sign of active tuberculosis infection;

- The spirometer, hoses, and mouthpiece adapters will be changed daily (see Chapters 2, Equipment, and 4, Quality Control, for details);
- The spirometry equipment is positioned so that the SP's mouth will always be higher than the orifice of the spirometer hose;
- The technologist will instruct participants to remove their mouth from the equipment immediately after each FVC maneuver and before inhaling again. As the mouthpiece is removed, the SP should direct it to the side. The air that is released from inside the spirometer will then not blow back into the SP's face. These practices will help prevent inhalation of a potentially infectious agent;
- After each exam, the technologist will have the participant discard the disposable filter and mouthpiece used during spirometric testing; and
- In the bronchodilator component administered by the physician, individual spacers will be used for each SP and discarded after use. The physician will also clean the bronchodilator casing and canister between each participant use.

5.1.3 Prevention of Electric Shock

The following safety precautions are taken to protect participants and MEC staff from electrical shock during spirometric testing:

- The spirometers are approved by the Underwriters Laboratories Inc. (UL). The UL is an independent, not-for-profit product-safety testing and certification organization whose services are widely used in the U.S. and internationally; and
- Electrical isolation of the participant from the spirometer is achieved through the use of a plastic hose and a cardboard mouthpiece.

5.2 Standing vs. Sitting During Spirometric Testing

To obtain the best results, participants should stand during the spirometric testing portion of the component. A nonrolling chair is kept in the exam room and will be placed behind the participant prior to testing should he or she need to sit between testing trials. Nevertheless, if a participant becomes faint or tired after initiating testing, the technologist may instruct him or her to sit for the remainder of the

exam. In these cases, the technologist will encourage the participants to sit up straight and will record the testing position in the OMI/NIOSH software as “Sitting.”

5.3 Comprehension or Language Difficulties

Some participants may have difficulty understanding the examination instructions. The technologist should use extreme caution when attempting to conduct the spirometry component on these participants. For instance, an inability to correctly answer the safety exclusion questions threatens to compromise the participant’s capacity to safely perform spirometric testing. Failure to follow the correct procedures regarding the positioning and use of the mouthpiece during spirometric testing may raise the risk of infection transmission between participants.

A Spanish version of safety exclusion questions and exam instructions will be made available for use with Spanish-speaking participants. If the technologist is not English-Spanish bilingual, a Spanish interpreter will be assigned to interpret for the participant and the technologist during the exam. If the participant speaks a language other than English or Spanish, arrangements will be made ahead of the spirometry exam to identify an appropriate interpreter. Otherwise, as in the case of other forms of comprehension difficulties, if the participant cannot understand your directions enough to provide valid responses, end the component and code the status as “Not Done” due to “Communication Problem.”

5.4 Emergency Procedures

The spirometry examination should ordinarily pose little risk to the safety of the participant. Incorporation of the medical exclusion criteria into the pre-examination interview further minimizes safety risks. In rare cases, the participant may hyperventilate and become dizzy during spirometric testing. Any participant who feels faint should be guided onto the chair with his or her head down towards the knees, and encouraged to breathe slowly and deeply until he or she recovers.

If the participant fails to recover normal breathing, faints, or reports feeling ill, the technologist should summon the MEC manager and physician immediately. The physician will assume command of the emergency response. The physician should always be consulted if there is any question regarding the participant’s safety status during the exam. The NHANES mobile exam center has a well-

developed emergency response protocol that will be implemented in the event of any emergency. Refer to the *NHANES Safety Issues and Emergency Procedures Manual* for complete details.

Appendix A

NIOSH Spirometry System Design Criteria

APPENDIX A

NIOSH SPIROMETRY SYSTEM DESIGN CRITERIA

The spirometry system used in the survey is required to meet the most recent Recommendations and Guidelines established by NIOSH and the American Thoracic Society for the performance and interpretation of spirometry. For reference purposes only, this appendix describes the basic design criteria for the spirometry system that will be used in the NHANES pilot and main study.

A.1 Output

The OMI/NIOSH software system will allow capture of the raw data curves for each expiratory maneuver. The following list of ATS spirometric parameters will be captured:

Table A-1. List of ATS Spirometric Parameters

ID (patient identification)
Data type (SP followed by E = expiratory or I = Inspiratory, followed by S = single or B = best curve)
Barometric pressure (mmHg)
Temperature (°C) used in BTPS calculation
FVC quality attribute (A, B, C, D or F)
FEV1 quality attribute (A, B, C, D or F)
Effort attribute (A, B, C, D or F)
Interpretation code (see ATS interpretation scheme)
Deleted maneuver (Y or N)
Acceptable maneuver (Y or N)
Technician quality control code (A, B, C, D or F)
Plateau achieved (Y or N)
Review (N or R for “needs review” or “was reviewed”)
Date of review (DD/MM/YYYY)
Reviewer initials
BTPS factor (x.xxx)
Calibration date (DD/MM/YYYY)
Calibration time (HH:MM)
Calibration result (P or F for “passed” or “failed”)
Calibration Date (DD/MM/YYYY)
Calibration Time (HH:MM)
Technician ID (technician identification code or initials)
Maneuver number
Age (integer years)
Height (cm)

Table A-1. List of ATS Spirometric Parameters (continued)

Weight (kg)
Sex (M or F)
Race (2-character race code)
Reference values correction factor (x.xx, 1.00 for no correction)
Testing position (standing, sitting, or supine)
Test type (pre-, post-, bronchodilator, methacholine concentration or dose)
FVC (mL)
Extrapolated volume (mL)
FEV 0.5 (mL)
FEV1 (mL)
FEV 3 (mL)
FEV6 (mL)
PEF (mL/s)
FEF25-75% (mL/s)
Forced expiratory time (s)
Time to PEF (ms)
Predicted FVC (mL)
Predicted FEV1 (mL)
Predicted FEV6 (mL)
Predicted FEV1/FVC% (xxx.x%)
Predicted FEV1/FEV6% (xxx.x%)
Predicted PEF (mL/s)
Predicted FEF25-75% (mL/s)
Lower Limit of Normal FVC (mL)
Lower Limit of Normal FEV1 (mL)
Lower Limit of Normal FEV6 (mL)
Lower Limit of Normal FEV1/FVC% (xxx.x%)
Lower Limit of Normal FEV1/FEV6% (xxx.x%)
Lower Limit of Normal PEF (mL/s)
Lower Limit of Normal FEF25-75% (mL/s)
Interpretability Code: “Within normal limits”, “Outside Normal Limits” or “Not Interpretable”

A.2 Accuracy

The ATS recommends that the spirometer have accuracy for FVC and FEV1 of at least 3 percent of reading or 50 milliliters, whichever is greater. While it is desirable to use a spirometer system that exceeds the ATS accuracy requirements, an accuracy better than 1 percent of reading has little practical advantage — considering a within subject coefficient of variation for FVC between 2.5 to 3 percent.

The dry rolling seal spirometer with an analog potentiometer has an accuracy of approximately 3 percent, or only slightly within the ATS accuracy requirement. To improve the spirometer accuracy, a digital shaft encoder is used to convert the volume displacement to a digital signal, replacing the analog potentiometer. To further improve the accuracy of the spirometer system, a linear model is used to estimate the volume as a function of the counts obtained from the digital shaft encoder ($Y = mx + b$). In the current survey, a model was chosen with an intercept term (b) or offset volume to improve the accuracy of the spirometer, particularly at volumes greater than 0.5 liters. It is possible to force the line through zero ($y = mx$), but this model will result in an apparent nonlinearity at higher volumes and corresponding degradation in accuracy. Typically, the intercept term is 50 ml with a gain or slope of 2.65 milliliters per count ($r > 0.9999$). The model is not used in the calculations of the extrapolated volume. Extrapolated volumes are usually less than 0.5 liters and using a 50 ml intercept term below 0.5 liters is inappropriate. For this reason, an intercept term or offset volume of approximately 15 ml is used in the model for extrapolated volume calculations. Since the raw volume time curve is saved, other correction algorithms can be used “off-line.”

An 11.5 Hz digital filter is used to filter the volume time signal to eliminate the high frequency noise. This filter has no effect on the volume parameters (FVC, FEV1, etc.) but does improve the accuracy of the flow parameters (Peak Flow, FEF50%, etc.). Flow parameters are calculated using the algorithm described in the ATS 1987 revised spirometer recommendations. NIOSH test results indicate that using this technique improved the spirometer system accuracy to better than 1.5 percent of reading. This falls well within the ATS accuracy recommendations of 3 percent of reading or 50 milliliters, whichever is greater.

A.3 Return Spring

The spirometer system is designed to use the return spring (“negator”) that is standard on most dry rolling seal spirometers. The advantages of using the return spring are: (1) the spirometer piston is returned to the zero position at the end of each maneuver, reducing the time required to test a subject; (2) any leak in the spirometer or between the subject and his or her mouthpiece is easily detected because of the obvious loss in volume as a result of the positive pressure (0.4 cm H₂O) generated by the return spring; (3) there is a clear indication when the subject comes off the mouthpiece, avoiding the slight increase in volume which can occur in some dry rolling seal spirometers when not used with a return

spring (due to seal “memory”); and (4) the spirometer is always stored with minimal volume in the spirometer which eliminates the development of seal memory.

The primary disadvantage of using the return spring is that a minimal pressure is necessary to cause the piston to start its displacement. However, the static pressure is small (approximately 0.4 cm H₂O) and constant over the entire volume range of the spirometer. The maximum pressure by the ATS is less than 1.5 cm H₂O.

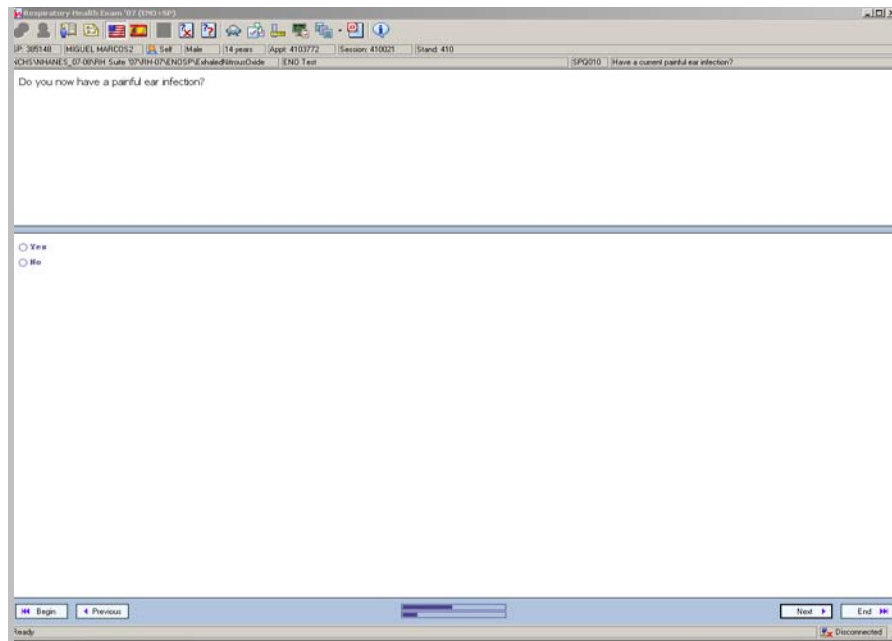
The intercept term and the calibration factor (gain) for each spirometer is estimated through testing of each spirometer. Upon system power-up, the computer software enters a preset code containing the spirometer's calibration factor and offset volume. This code also has provision for checking for possible errors during entry of the code. The software contains calibration codes for all spirometers used in the survey, so that spirometers can be interchanged during MEC operations.

Appendix B

Screenshots for Spirometry Safety Exclusion Questions

Safety Exclusion Questions

SPQ.010



Respiratory Health Exam '07 (END+SP)

SP: 36148 | MSUEL NARCOSIS | Self | Male | 14 years | Appt: 4103772 | Session: 410025 | Stand: 410

RH Suite '07\RH-07\END\SP\ExhaledNitrousOxide | END Test | SPQ010 | Have a current painful ear infection?

Do you now have a painful ear infection?

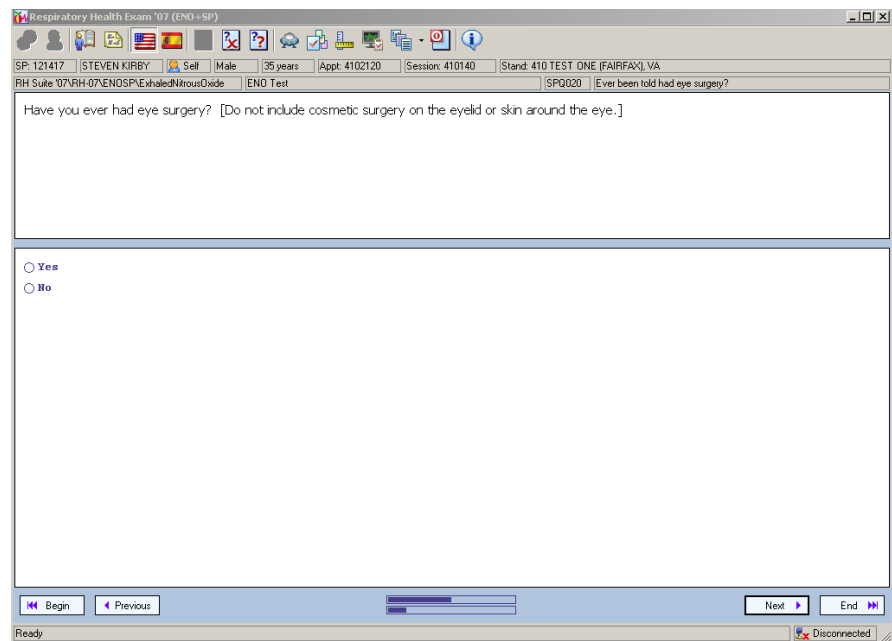
☐ Yes

☐ No

Begin Previous Next End

Ready Disconnected

SPQ.020



Respiratory Health Exam '07 (END+SP)

SP: 121417 | STEVEN KIRBY | Self | Male | 35 years | Appt: 4102120 | Session: 410140 | Stand: 410 TEST ONE (FAIRFAX) VA

RH Suite '07\RH-07\END\SP\ExhaledNitrousOxide | END Test | SPQ020 | Ever been told had eye surgery?

Have you ever had eye surgery? [Do not include cosmetic surgery on the eyelid or skin around the eye.]

☐ Yes

☐ No

Begin Previous Next End

Ready Disconnected

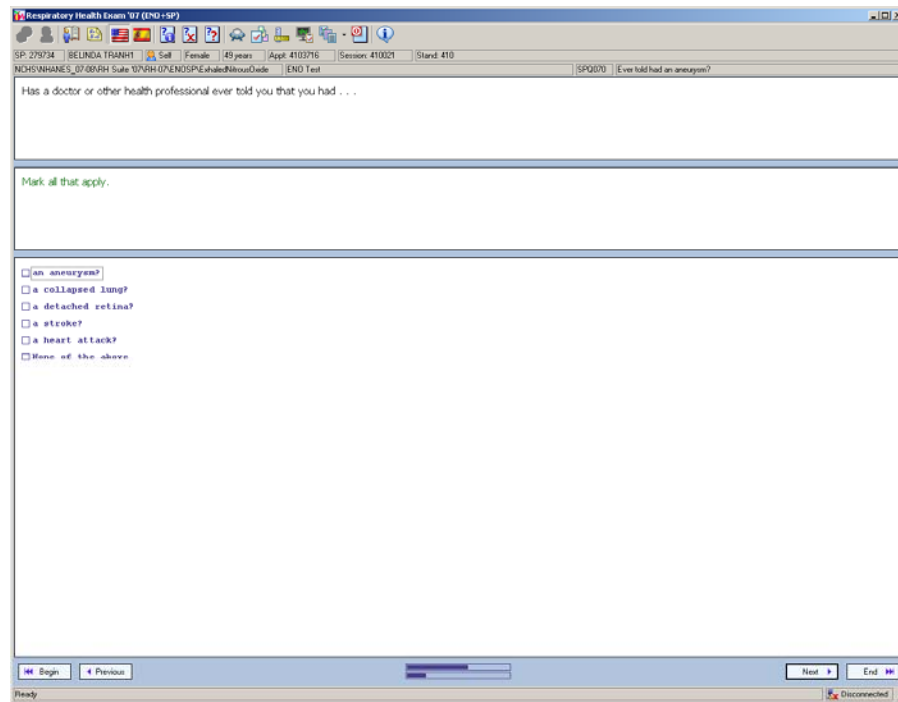
SPQ.040

The screenshot shows a software window titled "Respiratory Health Exam '07 (ENO+SP)". The patient information bar at the top includes: SP: 385148, MIGUEL MARCOSZ, Self, Male, 14 years, Appt: 4103772, Session: 410021, Stand: 410. The question bar displays: "Have you ever had open chest or abdominal surgery?". The question text is "Have you ever had open chest or abdominal surgery?". Below the question, there are two radio button options: "Yes" and "No". The "No" option is selected. At the bottom of the window, there are navigation buttons: "Begin", "Previous", "Next", and "End". A status bar at the very bottom shows "Ready" and "Disconnected".

SPQ.060

The screenshot shows a software window titled "Respiratory Health Exam '07 (ENO+SP)". The patient information bar at the top includes: SP: 201113, KATIE HOGAN, Self, Female, 50 years, Appt: 4104828, Session: 410011, Stand: 410 TEST ONE (FAIRFAX), VA. The question bar displays: "Did you or anyone in your household have tuberculosis in the past year?". The question text is "Did you or anyone in your household have tuberculosis in the past year?". Below the question, there are two radio button options: "Yes" and "No". The "No" option is selected. At the bottom of the window, there are navigation buttons: "Begin", "Previous", "Next", and "End". A status bar at the very bottom shows "Ready" and "Disconnected".

SPQ.070



Respiratory Health Exam '07 (END-SP)

SP: 279734 BELINDA TRANH Self Female 45 years Appt: 4103716 Session: 410021 Stand: 410

NCHS WHANES_07-08-PR Suite 107-PR-07-ENOSPE-ahedNrousOade END Test SPQ.070 Ever told had an aneurysm?

Has a doctor or other health professional ever told you that you had . . .

Mark all that apply.

☐ an aneurysm?

☐ a collapsed lung?

☐ a detached retina?

☐ a stroke?

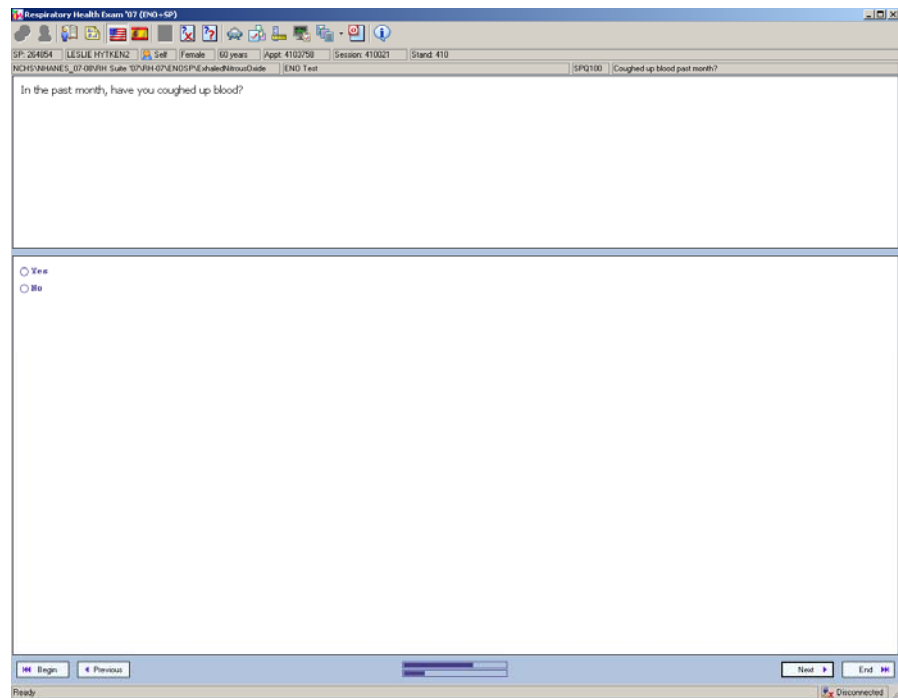
☐ a heart attack?

☐ None of the above

Begin Previous Next End

Ready Disconnected

SPQ.100



Respiratory Health Exam '07 (END-SP)

SP: 284854 LESLIE HYIENG Self Female 60 years Appt: 4102758 Session: 410021 Stand: 410

NCHS WHANES_07-08-PR Suite 107-PR-07-ENOSPE-ahedNrousOade END Test SPQ.100 Coughed up blood past month?

In the past month, have you coughed up blood?

☐ Yes

☐ No

Begin Previous Next End

Ready Disconnected